

USE OF HERBAL PRODUCTS, PRESCRIBED MEDICINES AND
NON-PRESCRIBED MEDICINES BY COMMUNITY-DWELLING
OLDER WOMEN

By

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By

Saun-Joo Lee Yoon

To my husband, Sung-Hwa,
and daughters, Alyssa and Hyunji

for

their love, patience, and encouragement

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Major Department: Nursing

As alternative health care is becoming more prevalent among persons in the United States, the use of herbal products is on the increase. Although herbal products are considered to be natural, these products have not been subjected to scientific clinical studies and, therefore, have not been FDA approved. The number of women aged 65 years and older in the US using herbal products is unknown. The purpose of this research is to explore the use of herbal products for medicinal purposes and to compare differences in demographic characteristics and health status between the herbal product users and non-users among community-dwelling older women. Sampling criteria were

women 65 years and over and living independently in a North Central Florida county. A random sample was selected from a list of 8,344 women 65 years and over obtained from the State Department of Highway Safety and Motor Vehicles. Structured interviews were completed on 86 subjects.

The interview questionnaire was comprised of three parts including health status and use of conventional medicines, use of herbal products, and demographic data. Data indicated that herbal products were used by 45.3% of the sample in the past 12 months. The total sample reported using a mean of 3.2 prescribed medicines and 3.8 non-prescribed medicines per person. The mean number of herbal products used by the sample was 2.5. The sample reported using a total of 98 herbal products. Subjects reported only 28% of the total number of herbal products used to their health care providers. No differences in demographic characteristics and health status were found between users and non-users of herbal products except in the area of memory problems. More herbal product users claimed memory problems than non-herbal users. It is important for health care providers to be knowledgeable of the use of herbal products in order to provide comprehensive health care to older women and to prevent unintended herbal-drug interactions.

CHAPTER I INTRODUCTION

Persons who are 65 and older comprise the fastest growing age group in the United States. Among 249 million people in the United States, 34 million are aged 65 and older (U.S. Bureau of Census, 1990). In the 65 years and older population, women outnumber men and this gap widens with increasing age (Cobbs & Ralapati, 1998). Older women in this age group have a higher disability rate and are more likely than men to live longer with chronic conditions (Kart, 1994).

Although persons 65 and older represent about 14% of the American population, they consume three times more prescription drugs than their younger counterparts (Gormley, Griffiths, McCracken, & Harrison, 1993). Four out of five people aged 65 and older have at least one chronic disease (Delafuente, 1991), and persons in this age group have almost twice the risk of iatrogenic disease and visit the clinics more often than do younger people (Lamy, 1986). Researchers show that community-dwelling elderly use an average of 4.4 drugs including prescription and

non-prescription drugs, and about 85% of these persons take two or more drugs (Follow, Stoller, Foster, & Duniho, 1994).

Many elderly people are dependent on conventional drug therapy to treat their chronic conditions and to maintain their health. The goals of drug therapy in the elderly are to (a) alleviate pain, (b) improve functional capacity, (c) promote quality of life, and (d) prolong life (Sloan, 1992). Multiple drug use in the elderly, even when each drug has a therapeutic purpose, can increase the risk of significant drug-related problems such as adverse drug reactions or drug-drug interactions (Noyes, Lucas, & Stratton, 1996; Sloan, 1992). While the use of multiple prescription and non-prescribed drugs among the elderly has been studied extensively (Chrischilles et al., 1992; Fillenbaum, Horner, Hanlon, Landerman, Dawson, & Cohen, 1996; Helling, Lemke, Selma, Wallace, Lipson, & Cornori-Huntley, 1987; Stewart, Moore, May, Marks, & Hale, 1991), little is known about the use of herbal products by this age group and how herbals react when taken with prescribed and/or non-prescribed medicines.

Recently, herbal products have increasingly received attention in the United States as complementary and

alternative medicine. Many researchers have used different terms to explain complementary and alternative medicine (CAM) such as unconventional, alternative or complementary, unproven, and unorthodox therapies. Eisenberg, Kessler, Forster, Norlock, Calkins, and Delbanco (1993) defined CAM as medical interventions not taught widely at U.S. medical schools or those not generally available at U.S. hospitals (i.e. acupuncture, chiropractic, and herbal medicine). The definition of CAM was further refined in the CAM Research Methodology Conference in 1995 as a broad domain of healing resources that comprises all health systems, modalities, and practice other than a dominant health system of a particular society in a given historical period (Panel on Definition and Description, CAM Research Methodology Conference, April 1995, 1997).

Recently, attention to CAM has been given by governmental health agencies. Examples include the establishment of the Office of Alternative Medicine (OAM) in National Institutes of Health (NIH) in 1992, and the passage of new regulation of herbal products as dietary supplements in the Dietary Supplement Health and Education Act (DSHEA) in 1994 (Taylor, 1996). Even before the passage of new regulations on herbal products in 1994, sales of

herbal products in the United States in 1991 were estimated at over one billion dollars (McCaleb, 1993). Although it may not necessarily reflect the actual use of CAM including herbal medicines, changes in the regulation of herbal products and more research focused on CAM certainly bring higher public interest than ever before.

In the United States, one in three study participants reported using at least one unconventional therapy in the past year (Eisenberg et al., 1993). In the same study, three percent of Americans surveyed used herbal medicines during the past twelve months while approximately 80% of the worldwide population were estimated to depend on traditional herbal medicines (World Health Organization, 1993). According to Eisenberg and colleagues (1993), the majority of people used unconventional therapies for chronic medical conditions, but not for life-threatening situations. Eisenberg and colleagues (1993) inferred that a substantial number of unconventional therapies were used for nonserious medical conditions, health promotion, or disease prevention.

Because of the variability of complementary and alternative medicines, natural health food stores selling herbal products are expanding businesses in the United

States. The botanical industry has grown from almost nothing to a \$1.5 billion industry in 20 years and is expanding at a rate of 15% a year (Marwick, 1995). Herbal products are becoming more familiar to the public because these products are considered to be natural and safe to use without adverse effects and are easy to obtain in the natural health food stores.

Today, people have access to a wide availability of herbal products and many of these products have been imported from foreign countries without strict safety regulations. Herbal products can be toxic and can sometimes be mixed with toxic ingredients with or without knowledge of the user. People can suffer adverse effects because of misinformation about products, possible interactions with conventional drugs, and substance overdose. Because the elderly are a group of people using herbal products for their health care, they are most at risk of suffering adverse effects by using these herbal products alone or combined with conventional drugs.

Because of the increased attention and consumption of herbal products, there must be more research to study the patterns of herbal use alone or with prescribed and/or non-prescribed medicine. More needs to be known about the

prevalence and the reasons for taking herbal products among the elderly as well as possible interactions between drugs of conventional medicine and herbal products.

Problem Statement

It is known that there are altered pharmacological mechanisms and decreased functional capacity of the major organ systems with aging (Montamat, Cusack, & Vestal, 1989). However, people who are aged 65 and older consume three times more prescription drugs than those under 65 (Gormley, Griffiths, McCracken, & Harrison, 1993). In addition to prescribed medications, the older adults are, also, frequent users of nonprescription drugs (Pollow, Stoller, Foster, & Duniho, 1994). The overall incidence of adverse drug reactions or interactions in the elderly is two to three times higher than the occurrence in their younger counterparts (Nolan, & O'Malley, 1988). These figures, however, do not include reaction or interaction with the use of herbal products.

Most older persons have at least one chronic condition and many have multiple conditions. According to the Administration on Aging, the most frequently occurring conditions per 100 elderly in 1994 included arthritis (50), hypertension (36), heart disease (32), hearing impairments

(29), cataracts (17), orthopedic impairments (16), sinusitis (15), and diabetes (10). Women who are aged 65 and older have the highest rate of chronic conditions such as arthritis (U.S. Department of Health and Human Services, 1997).

Eisenberg and colleagues (1993) pointed out that the use of unconventional therapies was not limited to the person's principal medical condition as adjuncts to conventional therapy, but extended to nonserious medical conditions, health promotion, or disease prevention. A full one-third of their study respondents who used unconventional therapies did not use these therapies for any of their principal medical problems (Eisenberg et al., 1993).

According to the earlier study by Eisenberg and colleagues (1993), prevalence rate of persons 18 years and older who use herbal products in the United States is three percent. However, since the Dietary Supplement Health and Education Act in 1994, the use of herbal products has increased; and since that time, researchers have found an increasing prevalence of herbal product use among persons in the United States. The World Health Organization estimated that traditional herbal medicines were the most

frequently used types of therapies for the majority of people in the world.

There were controversial results relating to the prevalence of reported use of herbal medicines among age groups in studies conducted in the United States (Eisenberg et al., 1993; Frate, Croom, Frate, Juergens, & Meydrech, 1996). Frate and colleagues (1996) stated that over 70 percent of the adults in their sample used at least one plant-derived medicine during the past year, while three percent of the study population used herbal therapies in the study by Eisenberg and colleagues (1993). Differences in study results may occur because of research methodology, definitions of herbal medicine and plant-derived therapies, and settings of data collection.

The use of herbal products has been studied in certain types of illnesses. Researchers showed the use of herbal products among AIDS patients (Greenblatt, Hollander, McMaster, & Henke, 1991; Kassler, Blanc, & Greenblatt, 1991), Alzheimer's patients (Coleman, Fowler, & Williams, 1995), rheumatoid arthritis patients (Boisset & Fitzcharles, 1994), and cancer patients (Cassileth & Chapman, 1996).

While researchers reported the use of herbal products among disease specific groups of people, very little is

known about the prevalence of use of herbal products among the elderly residing the community. Also, little information is available related to the potential adverse effects of herbal products and possible interactions between conventional drugs and herbal products in the elderly.

Research Aims

The purpose of this research is to study the use of herbs and/or herbal products for medicinal use as well as the possible interactions between herbals with prescribed and/or non-prescribed medicines among community-dwelling older women.

Specific Aims

1. To identify the prevalence of use of herbal products and/or herbs among community-dwelling women 65 years and older.
2. To identify the purpose for which women 65 and older take herbal products and/or herbs and to determine for which physical symptoms or health conditions women most likely take herbal products.
3. To describe the frequency of use of herbal products and/or herbs and whether herbal products and/or herbs are used alone or in combination with prescribed and/or non-prescribed medicines.

4. To identify the sources of information related to herbal products and/or herbs used by women 65 years and older.

Research Hypotheses

1. There are differences in demographic characteristics between herbal users and non-herbal users among women aged 65 and older.
2. There are differences in health status between herbal users and non-herbal users among women aged 65 and older.

Research Questions

1. What is the prevalence of women aged 65 years and over who use herbal products and/or herbs?
2. What is the purpose for taking herbal products and/or herbs by women aged 65 years and over? Do older women take herbal products more for prevention or for treatment of symptoms?
3. What is the frequency of use of herbal products by older women? Do women who use herbal products use them continuously over time or on an as needed basis? Do women who use herbal products use them alone or in combination with prescribed and/or non-prescribed medicines?

4. What sources do women 65 and over use to obtain information about the use of herbal products?

Operational Definition of Terms

For the purpose of this research, terms are operationalized as follows:

1. Complementary and Alternative Medicine (CAM) is defined as a broad domain of healing resources that comprises all health systems, modalities, and practice other than a dominant health system in the United States. CAM is used interchangeably with alternative medicine, unconventional, complementary, or unorthodox therapies.
2. Older woman is defined as a woman 65 years and older.
3. Drugs of conventional medicine include the prescribed and non-prescribed medicines. Non-prescribed medicines include vitamins and minerals. Drugs of conventional medicine can be used interchangeably with conventional drugs.
5. Herb is defined as a plant or plant part valued for its medicinal qualities.
6. Herbal product is defined as a product that (a) is excluded from definition of 'drug' by FDA; and (b) is not labeled as a vitamin, a mineral, or food additive; and (c) contains active ingredients aerial or underground parts of plants, other plant material in a

crude state or plant preparation, or combinations preparations; or (d) contains natural organic or inorganic active ingredients, which are not of plant origin by tradition, a concentrate metabolite, constituent, or extract. Herbal products include herbs hereafter.

7. Conventional medicine is defined as a dominant health system in the United States which is widely taught at U.S. medical schools or which is generally available at the U.S. hospitals.
8. Polypharmacy is defined as the use of four or more drugs, including both prescribed and non-prescribed drugs, by a single person.

Assumptions

1. Participants have some knowledge of their health status, including herbal products and drugs used for health promotion and care.
2. Participants can identify reasons to choose or not to choose herbal products.
3. Participants have access to various sources of information about herbal products.
4. Participants may feel that it is not necessary to communicate the use of herbal products to their physicians or other regular health care providers,

because herbal products are from natural sources and considered as dietary supplements.

5. Although herbal products are considered to be safe and beneficial for maintaining or promoting health conditions in general, certain herbal products may have potential toxicity or may interact with certain conventional drugs.

Limitation

The generalizability of results of this study is limited to older women who live independently in north Florida. However, the population is believed to be similar to the populations of older white community-dwelling women in other parts of the United States.

Summary

Persons aged 65 and older are a rapidly growing group in the United States. In an aging population, there is an increase in the number of persons with chronic illnesses who need health care services. As persons age, there is a greater population of women than of men; and women have a higher disability rate than their male counterparts.

The known facts about herbal products are as follows. First, complementary and alternative medicines are receiving increased attention by society. Second, consumption of herbal products has increased and continues

to increase among people. Third, few toxicities and benefits of herbal products have been studied and recognized. Finally, primary physicians and other health care providers are not always aware that patients are taking herbal products. That is not only because patients lack knowledge about the contradistinctions of herbal products and conventional drugs but also because primary physicians or health care providers do not ask the patients about the use of herbal products.

However, there are facts that are not known clearly. Since herbal products are more likely to be used for chronic conditions and for maintaining and promoting health status, no known research data exist related to the use of herbal products by older women. Although data are available reflecting the need for better communication between health care professionals and patients to prevent the polypharmacy causing the drug-drug interactions of conventional drugs, little is known about the information related to the prevalence of use of herbal products or potential side effects of herbal products among the older women.

It is important to enhance understanding related to prevalence of use of herbal products, specific purposes of using herbal products alone or in combination with drugs of

conventional medicine as well as differences between herbal product users and non-users among older women. The results of this research give a better understanding about the use of herbal products among older women and encourage extensive communication between health care providers and clients for comprehensive care, which results in improving the quality of life of older women.

CHAPTER II REVIEW OF LITERATURE

The review of literature pertaining to herbal products research includes summation of the following topics: (a) differences between alternative medicine and conventional medicine; (b) history of herbal products and their use; (c) prevalence of the use of alternative medicine; (d) choice between conventional and alternative medicines; (e) older women and health problems; (f) patterns of drug use among older adults; (g) polypharmacy among the elderly; and (h) toxicities of herbal products and possible interactions of herbal medicines with conventional medicines.

Differences between Alternative Medicine and Conventional Medicine

Alternative medicine is often defined as: (a) medical interventions not taught widely at U.S. medical schools or those not generally available at U.S. hospitals; (b) treatments which lack sufficient documentation in the U.S. for safety and effectiveness against specific diseases and conditions; and (c) practices that are not generally reimbursable by health insurance providers (Stalker,

1995). Seven categories of alternative medical practice are listed by the Office of Complementary and Alternative Medicines, the National Institute of Health (Workshop on Alternative Medicine, 1994). These include (a) mind-body interventions, (b) bioelectromagnetic therapies, (c) alternative systems of medical practice, (d) manual healing methods, (e) pharmacologic and biologic treatments, (f) herbal medicine, and (g) diet and nutrition. Mind-body interventions include psychotherapy, hypnosis, imagery, meditation, biofeedback, support groups, dance therapy, yoga, music therapy, art therapy, prayer, and mental healing. Mind-body intervention helps patients experience and express their illnesses in new ways by using placebo response and spirituality, as well as religion.

Bioelectromagnetics (BEM) is the science that studies how living organisms interact with electromagnetic (EM) fields and purports that changes in the body's natural fields may produce physical and behavioral changes. BEM includes blue light treatment, artificial lighting, electroacupuncture, electromagnetic fields, electrostimulation and neuromagnetic stimulation devices, and magnetoresonance spectroscopy.

Worldwide, 70% to 90% of human health care is delivered by alternative systems of medical practices,

varying from self-care according to folk principles to care by organized health care system based on an alternative tradition or practice. There are a variety of practices including acupuncture, traditional oriental medicine, ayurveda, environmental medicine, homeopathic medicine, Native American practices, naturopathic medicine, anthroposophically extended medicine, and Latin American rural practices.

Manual healing methods are based on the understanding that dysfunction of a part of the body affects secondary function of other body parts. These methods include osteopathy, acupressure, Alexander technique, chiropractic medicine, massage therapy, biofield therapeutics, and therapeutic touch (Workshop on Alternative Medicine, 1994).

Pharmacological and biological treatments are an assortment of drugs and vaccines not yet accepted by mainstream medicine, and include but are not limited to, anti-oxidizing agents, cell treatment, metabolic therapy, and oxidizing agents (Ozone, Hydrogen Peroxide). Diet and nutrition devised for the prevention and treatment of chronic disease include changes in dietary lifestyle, diet, Gerson therapy, macrobiotics, megavitamins, and nutritional supplements.

Herbal products are mostly a part of plants or plant products that have a long history of traditions in all cultures. Although many drugs commonly used today are of herbal origin, herbal products can be marketed only as food supplements in the United States. Despite the skepticism by Food and Drug Administration (FDA), a growing number of Americans are exhibiting interest in herbal preparations. The increased use of plant medicines has a potential benefit for improving public health, but issues related to safety, efficacy, and appropriateness of medicinal herbs need to be solved (Workshop on Alternative Medicine, 1994).

In contrast to alternative medicine, conventional medicine is the medical practice that is widely available at American medical schools or in U. S. hospitals, and is considered to be the world's standard health care system among most people in the United States. There are many differences between alternative medicine and conventional medicine. Conventional medicine is based on the empiricism that relies on a mechanistic model; wherein, body and mind are viewed as separate entities with illness being explained in terms of measurable physical phenomena. Therefore, the primary goal of conventional medicine is to bring about measurable objective improvement in disease states. In contrast, one of the primary goals of

alternative medicine is to alter the subjective state of the person, which can eventually promote objective improvements in disease states (Burg, 1996).

Conventional medicine and alternative medicine can also be distinguished by their approaches to the role of the patient in treatment (Burg, 1996), by administration of therapies, and by the interaction between the patient and health care provider (Workshop on Alternative Medicine, 1994). In biomedicine, patients receive the standardized treatment and medical advice on the basis of diagnosis or symptomatic categories. In this system, the patient-practitioner interaction is "physician centered." The physician, thus, is the authoritative expert and the patient is a receptive participant (Brunton, 1984). In contrast, alternative medical practitioners tend to individualize treatment and to create elaborate procedures for identifying individual suitability and sensitivity to the interventions. They often apply multiple treatment modalities and judge effectiveness by using subjective and patient derived outcomes (Jonas, 1993). Alternative systems of medicine emphasize a client-centered relationship and patient responsibility in the healing process, which can maximize the collaboration between the medical

practitioners and patients, thus enhancing the benefits of a therapy.

Although all complementary medicine practitioners do not share a common epistemology, several principles are common to most of their practices. These include emphasis on the: (a) Patients' feeling rather than their diagnosis; (b) Holistic view rather than conventional medical view: All aspects of the person (i.e. physical, emotional, mental, and psychosocial health, lifestyle, etc.) are interrelated and must be considered through the process of care; (c) Promotion of the use of a variety of therapeutic options for the purposes of prevention and treatment, and viewing treatment as a process; (d) Maintaining basic ethics of patient care such as do no harm; (e) Balance in a patient's body system, and relationship to other individuals, society, or environment; (f) Production of fewer side effects by using whole foods and herbs rather than using conventional drugs; and (g) Expectation that the patient is not a passive recipient but an active participant through the treatment process (Burg, 1996; Murray, 1994; Workshop on Alternative Medicine, 1994).

History of Herbal Products and Their Use

An herb is defined as a seed-producing annual, biennial, or perennial that does not develop persistent

woody tissue but dies down after flowering. The second definition is a plant or plant part valued for its medicinal, savory, or aromatic qualities (Merriam-Webster's Collegiate Dictionary, 1993). The herbs referred to in this paper are included under the second definition. An herbal medicine is a plant-derived material or preparation with therapeutic or other human health benefits, which contains either raw or processed ingredients from one or more plants (World Health Organization, 1993).

Herbal prescriptions are available for the entire range of medical ailments, including pain, hormonal disturbances, breathing disorders, infections, and chronic debilitating illnesses. These are classified according to their energetic qualities and are prescribed for their action on corresponding organ dysfunction, energy disorders, disturbed internal energy, blockage of the meridians, or seasonal physical demands (Workshop on Alternative Medicine, 1994).

Early humans treated illness by using plants, animal parts, and minerals that were not part of their usual diet. Herbal medicines using plants and plant products have been utilized in medical practice for thousands of years, and have made a great contribution to maintaining human health.

For example, the Ebers Papyrus, the preserved Egyptian manuscripts, were written around 1500 B.C. and contain 876 prescriptions made up of more than 500 different substances including many herbs. *De Materia Medica* written in the 1st century A.D. offers about 950 curative substances including 600 plant products and other 350 of animal or mineral origin in Greece and Rome (Ackernecht, 1973). This text explains a description of the plant, an account of its medicinal qualities, methods of preparation, and warnings about undesirable effects. The Arabs preserved a body of knowledge in the Muslim *materia medica*, which lists more than 2,000 substances, including many plant products (Ackernecht, 1973).

Herbs played an important role in Ayurvedic medicine in India, and were described in Ayurvedic books more than 2000 years ago. The history of Chinese herbal medicine can be traced to the end of the third century B.C. The *Encyclopedia of Traditional Chinese Medicine Substances*, the most definitive compilation of China's herbal tradition to date, has evolved from the *Classic of the Materia Medica* which was written almost 2,000 years ago. Traditional Chinese medicine influenced Korea and Japan and markedly simplified Japanese traditional medicine, called *Kampo* (Workshop on Alternative Medicine, 1994).

In contrast, the United States has a relatively short history of the use of herbal products compared to that of other countries. Early explorers of North America exchanged knowledge with the Native Americans to learn which herbs to use in the New World. Until the early 20th century, plants remained as a mainstay of country medicine, and were used not only by physicians to treat common ills, but also as important home remedies by many families (Buchman, 1980). A textbook of pharmacognosy contained hundreds of medically useful comments on herbs until the 1940s. As medicine evolved with advanced technology in the 20th century, remedies from natural resources were gradually forgotten in modern society. Today, however, many commonly used drugs are of herbal origin. About one-quarter of the prescription drugs dispensed by community pharmacies in the United States contain at least one active ingredient derived from plant material (Workshop on Alternative Medicine, 1994).

Recently, Americans have shown an increased interest in the use of herbs and herbal medicines due in part to the changing health care system's focus on preventive care as well as interest in natural therapies (Youngkin, & Israel, 1996). There are other factors contributing to an increased interest in herbal products in America. One factor is the wide availability of such products from European countries,

China, Japan, South America, and Mexico, in most U.S. health food stores. Secondly, people are willing to try herbs and herbal preparations for chronic illnesses or as an adjunct to other treatment. And, finally, herbs and/or herbal products are generally considered to be less toxic than drugs from conventional medicines (Workshop on Alternative Medicine, 1994).

It is now easier to gain access to herbal products since they are considered dietary supplements rather than a part of conventional drugs as a consequence of the Dietary Supplement Health and Education Act of 1994. In the United States, \$1.5 billion of herbs were sold in 1995, and their sales rate has been growing from 12% to 18% per year averaging about 15% a year (Gray, 1996). There were about 8,000 natural health food stores in the United States in 1995 (Marwick, 1995).

With an increased use of herbal products, safety and toxicity are becoming issues. Although it is generally perceived that natural products are safe, there are risks when these are used because not all herbal remedies are harmless. Herbs or herbal products can be incorrectly identified by manufacturers as nontoxic herbs. Since many herbal products are mixtures, some of them may be toxic, particularly if they are misused. Some ayurvedic botanical

products contain high levels of heavy metals that can cause toxic effects. Another threat posed by herbal remedies is a lack of proper knowledge in using them, which results in an overdose causing irreversible organ damage (Marwick, 1995). It is important for herbal product users to collect information about the herbal products prior to their use. Health care providers need be more attentive to thorough history assessments of their clients related to the use of herbal products as well as the use of conventional drugs.

Prevalence of Alternative Medicine and Herbal Products

Alternative medicine has gained in popularity and respectability in recent years, becoming widely used to promote or to maintain health, to treat diseases, to alleviate symptoms, and to prevent recurrence of illnesses. A 1990 national telephone survey revealed that 34% of Americans reported using at least one alternative medicine in the previous year including 10% who visited alternative practitioners, and spent \$13.7 billion on these visits. Americans made more visits to alternative practitioners (425 million) than to primary care physicians (388 million) (Eisenberg et al., 1993).

The results of the study by Paramore (1997) are consistent with that of Eisenberg and colleagues (1993). Paramore (1997) found that nearly 10% of the U.S.

population, almost 25 million persons, saw a professional in 1994 for at least one of the following four therapies: chiropractic, relaxation techniques, therapeutic massage, or acupuncture. The use of alternative medicines was correlated with poor health rather than maintaining or promoting health. The use of alternative medicines was frequently used among middle-aged whites who had more education and higher incomes (Eisenberg et al., 1993; Paramore, 1997). These researchers reported no significant gender differences in the use of four alternative medicines.

Alternative medicines were more frequently used to treat medical conditions such as back problems, insomnia, headache, anxiety, and depression (Eisenberg et al., 1993), and were also used for minor ailments, for health promotion, and as prophylaxis for recurrent problems (Murray & Shepherd, 1993). These therapies were generally used as adjuncts to conventional medicine rather than replacements for conventional medicine, (Eisenberg et al., 1993; Murray & Shepherd, 1993).

Overall, persons with chronic, nonspecific, and hard-to-treat illnesses are likely to be frequent users of complementary medicines. Researchers studying polypharmacy among patients attending an AIDS clinic found that 29% of

patients with AIDS used alternative medicines during the three month period prior to the interview, and the use of alternative medicines was associated with their stage of illness (Greenblatt, Hollander, McMaster, & Henke, 1991). The use of medicinal herbs was more frequent in HIV-infected patients than in the general population, which showed that 22% of 114 randomly selected HIV-infected patients reported using one or more herbal products in the past three months (Kassler, Blanc, & Greenblatt, 1991).

According to Coleman, Fowler, and Williams (1995), 55% of caregivers of patients with Alzheimer's disease reported that they had tried at least one alternative therapy to improve the patient's memory, including 11% who used herbal medicines. Although the proportion of cancer patients using alternative therapies is a smaller percentage compared with the percentage of all patients who do so, the prevalence of alternative cancer therapy in the United States ranged from a low of 6.4% to a high of 14.7% (Lerner & Kennedy, 1992).

A study in Canada showed that 66% of 235 Canadian patients with rheumatologic diseases had used alternative therapies in the preceding 12 months. The most frequently used alternative treatment modality was non-prescribed over the counter products including herbs, minerals, and topical remedies (Boisset, & Fitzcharles, 1994).

According to Eisenberg and colleagues (1993), the most common types of therapies used were relaxation techniques, chiropractic, and massage. Over a 12 month period, herbal medicines were used by only 3% of Americans surveyed (Eisenberg et al., 1993), while the World Health Organization estimated that 80% of the world population used herbal medicine for some aspect of primary health care (Farnsworth, Akerele, Bingel, Soejarta, & Eno, 1985).

Data from the rural, central Mississippi area (Frate, Croom, Frate, Juergens, & Meydrech, 1996) was close to the prevalence rate from World Health Organization, and showed that over 70% of the adults from the sample of 223 households used at least one plant-derived medicine during the past year. Herbal remedies were frequently used by people who were married, from larger households, of higher socioeconomic status, or who had consulted alternative healers (Brown, & Marcy, 1991). However, there is little factual evidence concerning the use of herbal medicines among the elderly and characteristics of users compared to those of nonusers.

Choice Between Alternative and Conventional Medicines

Despite the advances of conventional medicines, alternative therapies have received increased attention in the United States and other developed countries, and have

been chosen for use in treating various health problems by an increasing number of people (Eisenberg et al., 1993; MacLennan, Wilson & Taylor, 1996; Paramore, 1997). Compared to conventional medicine, alternative medicines rely heavily on the following factors: participation by patients in their own care; the relationship between the expectations of patients, cultural context, and lifestyle activities; and effects on therapeutic outcome of patients' choices of treatment (Workshop on Alternative Medicine, 1994).

In an earlier year, Kronenfeld and Wasner (1982) focused on the marginalized groups in society to study the relationship between alternative medicine and traditional folk medicine which has developed from ethnographic tradition. In recent studies, researchers have recognized that unconventional therapies are accepted and practiced by a significant number of people, and are believed to be a part of contemporary culture (Eisenberg et al., 1993; MacLennan, Wilson, & Taylor, 1996; Paramore, 1997).

Since significant numbers of persons have recognized the use of alternative medicine, many researchers have investigated factors associated with the choices of alternative therapies. Vincent and Furnham (1996) reported the principal reasons by patients for choosing alternative

medicine over conventional medicine. These reasons included

- (a) belief in the positive value of alternative medicine,
- (b) previous experience of ineffective treatment of conventional medicine, and (c) concern about the adverse effects of medical care.

Other factors influencing the choice of alternative medicine were the poor communication between patients and health care practitioners in conventional medicine, the willingness of alternative practitioners to discuss emotional factors, and the chance to take an active role in their treatment (Vincent and Furnham, 1996). Choices of alternative therapies were influenced by the prognosis for specific diseases such as AIDS, cancer, arthritis, or Alzheimer's disease (Boisset & Fitzcharles, 1994; Cassileth & Chapman, 1996; Coleman, Fowler, & Williams, 1995; Greenblatt, Hollander, McMaster, & Henke, 1991); dissatisfaction with the effectiveness of conventional medicine (Cassileth & Chapman, 1996; Sutherland & Verhoef, 1994); negative relationship to perceived health status and to health care providers (Sutherland & Verhoef, 1994); and a lack of confidence in conventional medicine (McGregor & Peay, 1996).

In summary, a single factor cannot be used to explain the choice of alternative therapies for one's care.

According to Kelner and Wellman (1997), many factors influence people in their choice of alternative therapies. Predisposing factors include level of education and age, enabling factors (i.e. income, knowledge, and accessibility of services), and the need for care. Kelner and Wellman (1997) point out individuals in their study who choose to try alternative therapies assume responsibility for their health and well-being. Kelner and Wellman (1997) also indicate that people do not make dichotomous choices between conventional medicine and alternative medicine. Rather, people choose specific kinds of treatments for specific problems, and many use multiple therapies concurrently. In addition, a wide range of possibilities of health care as well as public and private testimonials about successful alternative treatments result in more people deciding to use alternative therapies to cope with their problems and concerns (Kelner & Wellman, 1997).

Older Women and Health Problems

The majority of older Americans are women, and the number of older women will increase continuously. The number of women surpasses the number of men in the age range of 65 years and over, and this gap widens with increasing age (Cobbs & Ralapati, 1998). In 1994, there were 20 million older women and 14 million older men. Among

those 85 years and older, there are 44 men for every 100 women; women outnumber men by 100 to 26 over the age of 95; and four out of five centenarians are women. There is a rapid increase in the number of centenarians in the United States (U.S. Bureau of the Census, 1996).

Although a majority of older adults live independently in the community and consider their health to be good or excellent, chronic disease becomes more prevalent with age (Cobbs & Ralapati, 1998). Four out of five people aged 65 and older have at least one chronic disease (Delafuente, 1991). The use of multiple conventional drugs among older adults is a serious issue in the United States (Lamy, 1986; Noyes, Lucas, & Stratton, 1996). Even with functional disability increasing with age, most older women report that they are emotionally vital; but health status, level of disability, and sociodemographic status influence their emotional vitality (Penninx et al., 1998).

Many researchers, who studied the use of conventional drugs among community-dwelling older adults, reported gender differences in the use of conventional drugs (Chrischilles et al., 1992; Fillenbaum et al., 1996; Simons et al., 1992). Based on the data from the Established Populations for Epidemiologic Studies of the Elderly (EPESSE), Chrischilles and colleagues (1992) reported that

prescription drugs were used by 60-68% of men and 68-78% of women, while non-prescription drug use was 52-68% and 64-76% respectively (Chrischilles et al., 1992). While studying community-dwelling older adults, Simons and colleagues (1992) found that 76% of women and 56% of men who used multiple prescription drugs also used multiple non-prescription drugs.

Fillenbaum and colleagues (1996) and Simons and colleagues (1992) reported that female gender is one of the best predicting factors for the use of non-prescription drugs. Women reported taking more medications than men in each of these studies. Although Lassila and colleagues (1996) did not consider gender as a significant factor associated with the use of number of conventional drugs, most researchers who examined the use of non-prescription drugs accounted for 'female' as an important factor.

Gender difference was recognized in the types of health problems and health actions as well as in the use of conventional drugs. Musil (1998) reported that there are significant gender differences in psychological and physical health as well as the health actions among older adults residing in the community. The significant gender differences in psychological health were found in anxiety, depression, and body awareness; however, no gender

differences were found in self-assessed health and total number of health problems (Musil, 1998).

The gender differences in physical health are that women aged 65 years and over experience more arthritis, cataracts, hypertension, and asthma while their male counterparts have more problems with hearing, ulcers, abdominal hernias, and heart disease (Musil, 1998). By 80 years of age, 70% of women have two or more chronic conditions, most likely arthritis and hypertension, and other common chronic conditions such as heart disease and visual or hearing problems (Cobbs & Ralapati, 1998).

According to a study of health problems and related health actions among older adults (Musil, Ahn, Haug, Warner, Morris, & Duffy, 1998), frequent health actions in response to health problems are the use of non-prescription medicines (83%), self-care activities (72%), use of prescription medicines (53%), and professional consultation (43%). The gender differences in health actions suggest that women are more likely to use self-care while men incline towards seeking professional consultation (Musil, 1998) because, historically, women have played a major role in the healing process serving as caregivers of their own families (Burg, 1996). Self-care actions that are frequently used by community-dwelling older women include

taking non-prescription medicines, using home remedies, or making lifestyle changes (Musil, 1998).

The results of studies by Musil (1998) and Musil and colleagues (1998) are not surprising when considering frequent self-care actions by women including using home remedies. Burg (1996) states that most female patients may use some form of complementary medicine some time in their lives for their chronic health conditions; and women may use complementary medicines in combination with conventional medicines, which makes health assessment important to evaluate the potential interactive effects.

Although there are no known data specifically looking at women's use of complementary medicine in the United States, Burg (1996) suggested that certain groups of women may utilize complementary medicines based on gender-specific illness patterns and general knowledge about using complementary medicines. These groups of women who may use complementary medicines frequently are people with chronic, non-specific, or difficult for treating illnesses such as arthritis, depression, anxiety, HIV/AIDS, and cancer (Burg, 1996). In summary, it is important to examine health care practices among older women related to the use of herbal products as a part of complementary medicine since women live longer than men in their later stages of life with

increasing number of chronic health problems as they age. It is vital to understand the patterns of the use of herbal products in combination with conventional drugs in order to understand and prevent potential interactions between herbal products and conventional drugs. This knowledge and understanding assist health care providers to improve comprehensive health care for older women and subsequently, promote the quality of life of older women.

Patterns of Drug Use Among Older Adults

The population of the United States is 249 million including 34 million people aged 65 years and older (U.S. Bureau of the Census, 1990). The elderly are the fastest growing age group, and continue to grow faster than any other age group in the United States. Although most people are able to carry on their normal activities and functions up to the age of 75 or older, approximately four out of five people aged 65 and older have at least one chronic disease with an average of four diseases per person (Delafuente, 1991). There are many factors influencing drug use in the older adults including disease states, psychosocial factors, physicians who prescribe medications, and advertisement by the pharmaceutical industry (Stewart, 1995). Stewart (1995) states that other factors will influence patterns of drug use in the future such as the

development of new drug treatments with expanded coverage of prescription services by government and the influence of private insurers. Other factors associated with drug use in older adults are reported. These include prior drug use, number of health care visits, poorer health or self-perceived poor health, white race, female gender, impaired physical function, depression, hospitalization, insurance coverage, and smoking or drinking alcohol in previous year (Chrischilles et al., 1992; Fillenbaum et al., 1996; Lassila et al., 1996).

While there are great advantages of conventional drug therapy, there are problems associated with and resulting from conventional drug use by older adults. The use of conventional drugs for therapeutic purposes by older adults can contribute to significant drug-related problems because older adults are in an increased risk group due to impaired organ reserve capacity, multiorgan system dysfunction associated with multiple disease states, polypharmacy with drug interactions, and altered pharmacokinetics and pharmacodynamics (Sloan, 1992). Other problems associated with conventional drug use include polypharmacy, issues of compliance, drug-drug interactions in combination use of conventional drugs (Chenitz, Salisbury, & Stone, 1990; Lamy, 1986; LeSage, 1990; Noyes, Lucas & Stratton, 1996;

Stewart, 1995; Stewart & Cooper, 1994; Swonger & Burbank, 1995).

Several national and community-based studies have provided information on conventional drug use patterns among older adults. Patterns of prescribing practice of conventional drugs by health care providers for older adults have varied over time depending on the data collecting time and geographical differences (Stewart, Moore, May, Marks, & Hale, 1991). Data from the Florida retirement community of Dunedin, a relatively healthy and ambulatory group, were collected during 1978-1979 (May, Stewart, Hale, & Marks, 1982), and 1987-1988 (Stewart et al., 1991). The average number of drugs, including both prescription and non-prescription, taken by the older adults in Dunedin, Florida was 3.2 during the 1978-1979 period (May et al., 1982) and 3.7 in the ten-year overview of the Dunedin study (Stewart et al., 1991).

Researchers in the Iowa Rural Health Study gathered data during 1981-1982 from the community-based, generally elderly population and reported a mean of 2.9 prescribed medicines (Helling, Lemke, Semla, Wallace, Lipson, & Cornoni-Huntley, 1987). Other studies of drug use patterns in the older adults were conducted in North Carolina and Pennsylvania. These studies included urban as well as rural

areas as well as a significant proportion of African-Americans. Older adults in the Piedmont area of North Carolina were studied in 1986-1987 (Fillenbaum, Hanlon, Corder, Ziquba-Page, Wall, & Brock, 1993) and in 1989-1990 (Fillenbaum et al., 1996), and researchers reported a mean of 3.4 and 3.7 prescribed drugs per person in the two studies. In the MoVIES Project by Lassila and colleagues (1996), data were collected during 1987-1989 in the rural mid-Monongahela Valley community of Pennsylvania, a largely white (97%), blue-collar population. The result of the MoVIES Project showed subjects used a mean of 2.0 prescription drugs (Lassila et al., 1996).

Despite the differences in the time and the location of the study sites, findings are similar among these studies. When compared cross-sectionally and longitudinally, the proportion of the older adults who took conventional drugs increased with age, as did the number of medications taken (Chrischilles et al., 1992; Fillenbaum et al., 1993; Fillenbaum et al., 1996; Helling et al., 1987; Lassila et al., 1996; May et al., 1982; Stewart et al., 1991).

Polypharmacy

Polypharmacy has been recognized as a problem in the geriatric population (Gormley, Griffiths, McCracken, &

Harrison, 1993; Lamy, 1986; Noyes, Lucas, & Stratton, 1996; Shimp, Wells, Brink, Diokno, & Gillis, 1988). The elderly aged 65 and older, who represent only 14% of all American population, consume three times more prescription drugs than people under aged 65 years (Gormley, Griffiths, McCracken, & Harrison, 1993). The use of prescribed drugs has been projected to be 40% of the total drug expenditures in developed countries by year 2030 (Cusack, 1989). The older adults frequently use nonprescription drugs in addition to prescribed medications (Pollow, Stoller, Foster, & Duniho, 1994).

Polypharmacy has been defined in many different ways (LeSage, 1990; Michocki, Lamy, Hooper, & Richardson, 1993; Montamat & Cusack, 1992; Noyes, Lucas, & Stratton, 1996). In Healthy People 2000 (1990), polypharmacy was defined as the use of multiple prescription and nonprescription drugs, especially by elderly with chronic disease, while Noyes, Lucas, and Stratton (1996) considered multiple drug use synonymous with polypharmacy. LeSage (1990) defined polypharmacy as the concurrent use of several different drugs; whereas, Montamat and Cusack (1992) defined polypharmacy as the prescription, administration, or use of more medications than are clinically indicated in a given patient.

Other researchers (Michocki, Lamy, Hooper, & Richardson, 1993) considered polypharmacy only as the use of multiple drugs. Definition of polypharmacy by Michocki and colleagues (1993) was that particular patients received too many drugs, for too long a time, or in exceedingly high doses. Although there is neither a specific number of medications to define polypharmacy, nor a unanimously accepted definition of polypharmacy, polypharmacy consistently represents the use of multiple medications by a single patient (Stewart & Cooper, 1994).

Possible causes of geriatric polypharmacy are multiple health problems; multiple prescribers; noncurrent medication storage; prescription patterns of physicians; and self-medication behavior (LeSage, 1990). Since it has been known that older adults often take a large number of drugs for various reasons, possible adverse consequences of the use of multiple medications exist. These consequences are adverse drug reactions, drug interactions, medication errors, noncompliance, quality of life and functional decline, and high financial cost (LeSage, 1990; Stewart & Cooper, 1994).

Swonger and Burbank (1995) pointed out the problems of polypharmacy and drug misuse associated with both physician and client. Multiple drug regimens are often too

complicated or lack adequate rationale for each individual drug. Multiple chronic conditions of the elderly often require the use of more than one physician, which can lead to poorly coordinated care and adverse drug reactions.

Physician-centered problems are negative attitudes toward older people, difficulty in accurately diagnosing and dosing due to heterogeneity of the elderly, lack of client education about drugs and inadequate follow-up. Client-centered problems are unintentional resulting from a lack of knowledge or special instructions, forgetfulness in taking medicine, confusion, intentional omission, dosage adjustment, sharing drugs with other people, and stretching dosage requirements to save money (Swonger & Burbank, 1995).

Issues related to multiple drug use have been recognized in other studies (Col, Fanale, & Kronholm, 1990; Michocki, Lamy, Hooper, & Richardson, 1993; Ranelli & Aversa, 1994; Stewart & Caranasos, 1989). Ranelli and Aversa (1994) studied medication-related stress among family caregivers, and reported that 32% of the caregivers had medication-related problems and 19% had difficulty in managing medications. More than half of the caregivers experienced problems in the past year, including scheduling difficulties, compliance problems, difficulty organizing

medications for the patient, and lack of professional advice. Although only 7.7% of the total time was spent providing drug-related care by caregivers, medications did contribute to the stress of the caregiving experience (Ranelli & Aversa, 1994).

Compliance is another issue related to polypharmacy. Many factors were associated with compliance (Noyes, Lucas, & Stratton, 1996; Stewart & Caranasos, 1989). Among the factors related to compliance documented in literature, it was consistently mentioned that the number of medications taken and the complexity of the medication regimens were critical factors for patient's compliance.

One study of compliance rates related to dosage pattern, e.g. number of times per day, showed that compliance rate decreased when the number of times a medication was taken per day increased (Cramer, Mattson, Prevey, Scheyer, & Ouellette, 1989). Cramer and colleagues (1989) found only 39% of compliance rate with four times a day dosage schedule, while reporting 87% of compliance rate when medication was scheduled once a day for the elderly. Prescription of multiple drugs may increase noncompliance and cause adverse drug reactions or clinically significant drug interactions (Col, Fanale, & Kronholm, 1990). Adverse drug reactions are defined broadly by the United States

Food and Drug Administration (FDA) as any adverse event associated with the use of a drug in humans (Sills, Tanner, & Milstien, 1986).

According to Col and colleagues (1990), patients admitted to hospitals with medication noncompliance increased, when the number of different medications or the number of physician visits increased. Approximately 28% of hospital admissions among older adults were drug-related, and more specifically, were due to noncompliance (11.4%) and adverse drug reactions (16.8%). Although there are variations in reported hospitalization rates caused by adverse drug reactions, from 6.3% to 16.8% (Col, Fanale, & Kronholm, 1990; Colt, & Shapiro, 1989; Grymonpre, Mitenko, Sitar, Aoki, & Montgomery, 1988; Ives, Bentz, & Gwyther, 1987; Lindley, Tulley, Paramsothy, & Tallis, 1992), it is apparent that adverse drug reactions are serious and costly.

Toxicities of Herbal Products and Possible Interactions with Drugs of Conventional Medicine

In recent years, the use of herbal products has increased in developed countries, even though herbals have been a dominant form of health care in developing countries for many years. Although Eisenberg and colleagues reported that three percent of Americans were using herbal products

in the early 1990s, this number is assumed to be growing rapidly (Eisenberg et al., 1993).

The risk of potential toxicity of herbal medicines is accelerated by many factors. First of all, herbal medicines are not subject to standard Food and Drug Administration (FDA) tests for safety, effectiveness, and quality control because herbals are not considered conventional drugs but rather dietary supplements. Secondly, many herbal products are imported from foreign countries not mandating safety or manufacturing regulations. Finally, these medicines do not have the active or inactive ingredients listed on the package label (Anderson, 1996). Other factors contributing to the potential problems of using herbal products include (a) misidentification of a plant, or the unknown or ignored toxicity of a correctly identified plant; (b) persistent use of herbs known to be toxic; (c) difficulty in identification of chopped or mixed herbs; (d) variability in chemical constituents of herbs; (e) problems with nomenclature; (f) difficulty in establishing the cumulative effects of a plant; (g) contamination with heavy metals; and (h) possible adulteration with prescription drugs or with other substances (Drew & Myers, 1997; Huxtable, 1990).

Certain groups of people using herbal products are at higher risk of intoxication than other groups. Huxtable

(1990) points out that high risk groups are people using herbs or herbal products for a long time, consumers of large amounts or a wide variety of herbs, babies, the elderly, those with concomitant diseases and concurrent medications, and the malnourished or undernourished. Also, toxicities can be selective depending on gender and cultural groups (De Smet, 1995; Huxtable, 1990). Nevertheless, it is widely perceived that natural products are safe, and people will continue to use herbal medicines in ever-growing numbers (Marwick, 1995).

Although the risk of using herbal medicine is much less than that of using conventional medicine, many researchers suggest that using herbal products is not without risk and, consequently, safety of using these products needs to be considered.

Only nine herbal products are approved by the Food and Drug Administration (FDA) for selected applications (Youngkin & Israel, 1996). Recently, Youngkin and Israel (1996) reviewed the safety of herbal therapies compared to the safety and efficacy data derived from the German Commission E and other biomedical literature for selected commonly used herbs. Among the 56 herbal products reviewed, only seven were approved by the FDA; 36 were considered to be effective for one or more specified complaints by the

German Commission E; and only four were approved by both FDA and German Commission E (Youngkin & Israel, 1996).

Drew and Mayers (1997) proposed classification of adverse effects associated with herbal medicine into two categories, intrinsic and extrinsic effects. Intrinsic effects are those of the herb itself, and are characterized as type A and type B reactions for pharmaceutical purposes. Type A reactions are predictable and dose-dependent including effects with deliberate over-dose or accidental poisoning and interactions with pharmaceuticals. Type B are unpredictable and idiosyncratic reactions.

Extrinsic effects are not related to the herbal medicine itself, but to a problem in manufacture or compounding. Extrinsic effects may result from failing to adhere to a code of Good Manufacturing Practice and include contamination, misidentification, lack of standardization, substitution, adulteration, incorrect preparation and/or dosage, and inappropriate labeling and/or advertising. Extrinsic effects make it difficult for health care practitioners or users of herbal medicines to identify the correct herbal remedies or to assess the adverse effects (Drew & Mayers, 1997).

Information regarding toxicities and safety of herbal medicines is currently limited. The workshop on Alternative

Medicine (1994) listed the 20 most popular Asian patent medicines that contain toxic ingredients (see Appendix C). Other authors (Gray, 1996; Youngkin & Israel, 1996) summarized the scientific information and potential adverse effects of selected common herbal remedies. Currently, there is little information available related to interactions of herbal products in combination with the use of conventional drugs, although, it is assumed that there are possibilities of interactions between herbal products and conventional drugs (Drew & Mayers, 1997; Huxtable, 1990; Noyes, Lucas, & Stratton, 1996). More studies are needed to investigate the interactions between herbal products and conventional drugs.

Although the prevalence of the use of herbal products among older women is unknown, it is assumed that women aged 65 years and over consume more herbal products than their younger counterparts. Older women report more chronic health problems than younger women. Also, older women attempt to prevent deterioration of health in the later stages of their life. It is clear that older adults are susceptible to medication related problems because of their overall increased use of medication.

CHAPTER III METHODOLOGY

The purpose of this research was to study the use of herbs and/or herbal products for medicinal use and to compare the differences in demographic characteristics and health status between herbal product users and non-herbal users among community-dwelling older women. This chapter contains the research methodology and is comprised of five sections: research design, setting, sample, instruments, data collection procedure, and data analysis.

Research Design

This research utilized a cross-sectional and descriptive design to examine the prevalence of herbal product use, the types of the herbs used, and to identify the reasons for use of herbal products among women aged 65 and over. Subjects were categorized into two groups: Group 1, women 65 years and older who used herbal products and Group 2, women 65 years and older who did not use herbal products.

Setting

The setting for this study was a county located in North Central Florida.

Sample

It was statistically determined that a sample size of 84 subjects (42 subjects in each group) would provide the desired sensitivity to test the study hypotheses. This determination was based on a formulation of 95% power, a medium critical effect size of 0.40 for each of the dependent variables, and a significance level of 0.05 for a two-tailed test of means.

Sampling criteria were women who were 65 years and over and lived in the designated North Central Florida county. The principal investigator requested names and addresses of all women 65 years and older who resided in the selected county from the Division of Drivers' License, State Department of Highway Safety and Motor Vehicles. This list yielded 8,344 names and addresses of women aged 65 and older.

According to Waltz, Strickland, and Lenz (1991), 30% response rate was not unusual in mailed questionnaire surveys. Therefore, it was necessary to select at least three times the number of subjects needed for the total sample of 84 subjects to test the hypotheses. The investigator randomly selected 252 subjects from the total list utilizing the table of random digit (Rand Cooperation, http://www.rand.org/software_and_data/random/digits.txt).

After a random selection of names, 252 letters were mailed to the potential subjects, introducing the study and requesting participation in the study. A return self-addressed, stamped postcard was enclosed with each introductory letter. Of the 252 letters mailed, 53 subjects were included in the sample. Thirty-one more subjects were needed to attain a desired sample size of 84; therefore, 150 additional letters were mailed. From the second group of letters mailed, 33 subjects were included in the sample. Therefore, a total of 86 subjects completed the interview, resulting in 39 subjects in Group 1 (herbal product users) and 47 subjects in Group 2 (non-herbal users).

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (a) women who were 65 years and older living independently in the community; (b) currently living in the selected county; (c) ability to speak and understand English; and (d) able to verbally communicate with intact memory. Subjects who could respond to the requests for participation were considered to have adequate communication skills and memory ability. Exclusion criteria were as follows: (a) women who had severe health conditions, (b) resided in nursing home or other type of assisted living facility, (c) resided out of

the selected county, or (d) unable to contact after multiple attempts.

Instrument

The questionnaire was developed by the investigator because there were no known established questionnaires to perform this study. This questionnaire was used to obtain knowledge related to the prevalence and purpose of use of herbal products and how the herbal products were used with prescribed and non-prescribed medicines among women aged 65 and over. The questionnaire was comprised of three parts: (a) health status and use of conventional drugs including prescribed and non-prescribed medicines, (b) use of herbal products, and (c) demographic data.

The interview lasted approximately 15-30 minutes for the participants who did not use the herbal products, and were classified as group 2. The participants in this group were asked to answer part A and part C of questionnaire. The interview took approximately 30-45 minutes for the participants who responded 'yes' to the use of herbal products. These participants were classified as group 1. The participants in this group were asked to answer the entire questionnaire Part A (Health Information), Part B (Herbal Product Use Information), and Part C (Demographic Information).

Operationalization of Variables

Demographic Variables

Demographic characteristics of subjects were examined by six indicators: race, education, income, religious preference, insurance status, and marital status.

Race. Race was a categorical variable coded as white, black, Hispanic-nonwhite, and other.

Education. Education was categorized into four groups according to the number of years of formal education which the participants completed: less than a high school diploma, high school graduate, less than a college graduate, college graduate, and graduate school and higher.

Income. Income was the total annual household income of the participant. This measure was coded into four categories reflecting an income range from \$0.00 to over \$50,000: less than \$20,000, \$20,000 - \$34,999, \$35,000 - \$49,999, and \$50,000 and above.

Religion. Religious preference of participant was divided into five categories: None, Protestant, Catholic, Jewish, and other.

Insurance status. Status of insurance was categorized into five groups: None, Medicare, Medicaid, private insurance, and other.

Marital status. Marital status was coded into one of four categories reflecting the status of married, widowed, divorced/separated, or never married.

Herbal products variables

Eleven indicators were examined for the variables related to the use of herbal products. These were (a) number and type of herbal products used, (b) general purpose of using herbal products, (c) route, (d) preparation, (e) reasons used, (f) duration of use, (g) effectiveness of herbal products, (h) experience of adverse reactions by using herbs or herbal products, (i) sources of information for use of herbal products, (j) source of payment for herbal product, and (k) physician's awareness about using herbal product.

Number and type of herbal products used. The participant was asked to list the names of all the herbal products used in the last 12 months. The total number of herbal products used by each participant was counted. The mean number of herbal products used was calculated to measure the average number of herbal products used by the participants. Examination of frequencies identified the most common herbal products used.

General purpose of using herbs or herbal products.
The participant was asked the general purpose of taking

herbal products in the last 12 months. Purposes were categorized into one of three indicators: to treat illness, to maintain or prevent any possible health problems, and both treat and prevent illness.

Route. The route of using herbal products was a categorical variable identified as internal use and external use.

Preparation. Preparation was a categorical variable identified as self-prepared or purchased from a health food store or a regular retail store. Self-prepared herbal product defined the remedy that could not be used directly as it was obtained and thus required preparation time at home such as herbal tea. Purchased included the product that could be used directly without any preparation time after obtaining it such as an herbal tablet or a capsule.

Reasons used. Reasons to use herbal products were listed based on the types of health problems and were coded from 6 through 29. The codes starting from 6 through 28 were matched with specific illnesses on the Health Information Form in the questionnaire Part A (see Appendix A). Item number 29 was related to the use of herbal products for maintaining current health status or for preventing possible health problems.

Duration of use. Duration of using an herbal product was categorized into two groups: used continuously or used only when symptoms occurred. If the herbal product was used continuously, the participant was asked how long the product had been used. If the herbal product was used when symptoms occur, the participant was asked how many times in the last 12 months the product was used.

Effectiveness of herbal product. Effectiveness of herbal product had four indicators that included not at all, somewhat effective, very effective, and don't know.

Experience of adverse reaction. Experience of an adverse reaction from using an herbal product was a dichotomous variable coded zero/no when participant did not experience any adverse reaction and one/yes when the participant experienced any type of adverse reaction. If the answer was yes, the participant was asked what kind of adverse reaction she had experienced.

Sources of information. The participant was asked where she had obtained the knowledge about herbal products. The sources of information to use herbal products were categorized into nine groups: (a) family members; (b) friends and neighbors; (c) books or magazines; (d) TV, radio, and newspapers; (e) computer Internet; (f) health

food stores; (g) health care providers; (h) alternative care practitioners; and (i) others.

Health status variables

Eight indicators were utilized to identify the health status and the use of prescribed and non-prescribed medicines related to the health problems. These included (a) overall health, (b) physical health, (c) emotional health, (d) visit to doctor's or other health care provider's clinic, (e) existence of health problems, (f) seriousness of health problems, (g) number of medications used and medication identification, and (h) use of any herbal products.

Overall health, Physical health, and Emotional health.

A visual scale numbered one through five measured these three variables. One indicated a poor health status and five indicated an excellent health status.

Visit to a health care provider office or clinic.

The participant was asked two sets of questions. One question asked whether she had visited a health care provider office or clinic in the past 12 months. This dichotomous variable was coded no or yes. If the response was yes, a follow-up question asked was what health care provider she had visited. Seven categories included (a) family practitioner, (b) internal medicine, (c) surgeon,

(d) gynecologist, (e) nurse practitioner, (f) osteopathic doctor (D. O.), and (g) others.

Health problems. The participant was asked to identify her health problems from 23 different illnesses. The answer was coded zero when the problem did not exist and one if the problem existed.

Interference with normal activities. The participant was asked how seriously an illness interfered with her normal activities. Interference with normal activities was measured by a visual scale rating from one to five. One on the visual scale indicated that the health problem did not interfere with normal activities and five indicated that the health problem interfered greatly with normal activities.

Use of medications. The use of medications was a dichotomous variable coded zero or one for each identified illness. If the answer was yes, the participant was asked to name all prescribed and non-prescribed medications for each illness.

Use of herbal products. The use of herbal products was a dichotomous variable coded zero when herbal products had not been used and one when herbal products had been used for each identified illness.

Procedure

The investigator obtained the list of names and addresses of women aged 65 and over who resided in a North Central Florida County from the Department of Motor Vehicle and Safety in Tallahassee, Florida. The number of possible accessible population was identified as 8,344 women in the selected county. From the accessible population, at least 84 participants (42 subjects in each group) were required to meet the effect size.

The investigator used a table of random digits (Rand Cooperation: http://www.rand.org/software_and_data/random/digits.txt) to select a sample. The Investigator picked a starting point from the table of random digit by closing eyes and pointing pencil on one number. From the starting point of the table of random digits, 252 numbers between 0001 and 8,344 were selected. The numbers selected from the table were matched with the names from the list of accessible population.

Letters were mailed to all 252 potential participants to introduce the purpose of the study and request participation in the study. A return self-addressed, stamped postcard was enclosed with each letter. On the back of the postcard, the investigator requested the return response 'yes, I will participate in the study' and

requested a phone number to contact for interview, and 'no, I will not participate in the study.' From the first 252 letters mailed, 53 subjects met the inclusion criteria and completed the interview successfully. It was necessary to recruit at least 31 more subjects for this research study. The investigator repeated the same procedure of random sampling technique for the first mailing list except the first 252 names selected at the first round of sampling were excluded. For the second round of sampling, 150 subjects were calculated to meet the minimum necessary 31 subjects.

The investigator made a telephone call to each participant who returned the postcard indicating a willingness to participate in the study. The investigator had a brief telephone conversation with each subject to arrange the time and the meeting place for the interview. Prior to conducting a structured interview, an informed consent was obtained and a copy of the informed consent and business card of the chairperson were provided to each participant. Each participant was advised of her right as a research participant and the right to decline without penalty.

After an informed consent was obtained, the subject was asked to answer the questions related to health status,

the use of prescribed and non-prescribed medicines, the use of herbal products, and demographic information. The entire interview required approximately 15-45 minutes per subject. The participants were categorized into group 2, if they answered 'no' to question number A76 of Questionnaire Part A (Health Information). The participants in group 2 were not asked to answer Part B (Herbal Product Use Information) and continued to Part C (Demographic Information). The participants were categorized into group 1, if they answered 'yes' to the question number A76 of Questionnaire Part A (Health Information). The participants in group 1 were asked to answer both Part B and Part C. Data collection was completed when the total subjects numbered 86 (39 subjects in group 1 and 47 subjects in group 2). After completion of the interview, the data were entered into a data spreadsheet for analysis.

Data Collection

Data were collected to test the two research hypotheses and to answer the four research questions.

Research Hypotheses

Hypothesis One: There are differences in demographic characteristics of women aged 65 years and older between the herbal users and non-herbal users.

Demographic characteristics included education levels, incomes, insurance status, race or religion. To test hypothesis one, all participants were asked to answer the 'Health Information' questionnaire which included whether the participant used herbal products. If the participant used an herbal product, she was asked to answer the 'Herbal Product Information' questionnaire and the 'Demographic Information' questionnaire. If the participant did not use an herbal product, she was asked to answer the 'Demographic Information' questionnaire without 'Herbal Product Information'. Subjects were divided into two groups, one group of herbal product users and another group of non-users, to compare differences in demographic characteristics including education level, income, insurance status, race or religion.

Hypothesis Two: There is a difference in health status between herbal users and non-herbal users. Differences in health status between the two groups was tested by comparing illnesses, number of prescribed and non-prescribed medicines the participant used, perception of the participant's health status, and seriousness of interference of normal activities.

Research Questions

Question 1: What was the prevalence of use of herbal products among women 65 years and older?

Three types of information were collected to answer question 1: First, the participant was asked to name the all of the herbal products she had used in the last 12 months. The total number of herbal products used was counted to calculate the average number of herbal products used by all subjects. The most commonly used herbal products were identified within the total group of subjects. Secondly, to identify the period of time herbal products were used, each participant was asked how long herbal products had been used. She was also asked if she ingested the herbal by mouth (internally) or applied the herbal externally. The participant was asked whether she used the herbal on a continual basis or intermittently. Lastly, the participant was asked whether she purchased the herbal product from a store in a ready-to-take form or if she needed to prepare the herbal product prior to its use.

Question 2: What was the purpose for taking herbal products by women aged 65 years and older? Did older women take herbal products more for prevention or for treatment of symptoms?

The following information was collected to identify the purpose for which women 65 and older took herbal products and to determine for which physical symptoms or health conditions women most likely took herbal products. The participant was asked about her overall health, physical health, and emotional health status. The health status was measured by a visual scale with a range of one through five with one representing poor health and five representing excellent health status. The participant was asked the general purpose of taking herbal products to identify whether she took herbals to treat illness, to prevent possible health problems or to maintain her current health status, or for both treatment and preventive purposes.

To identify the specific reasons for using herbal products, the investigator identified common health problems of the subject. The subject was asked the specific reasons for taking the herbal products based on identified common health problems among older women. The perceived benefit of taking the herbal product was identified by the participant and then whether she felt that the herbal product was effective or ineffective. Data of perceived adverse reactions were collected including the types of adverse reaction experienced by the participant.

Question 3: What was the frequency of use of herbal products by older women? Did women who use herbal products use them continuously over time or on an as needed basis? Did women who use herbal products use them alone or in combination with prescribed and/or non-prescribed medicines?

Three types of information were collected to answer question three. First, the participant was asked the names of prescribed and/or non-prescribed medicines she took for her health problems. This information was later compared with the findings of question two to describe whether the herbal products were used alone or used in combination with the conventional drugs. Secondly, the findings of question three were compared with the findings of question two to describe the use of herbal products alone or in combined use with prescribed and/or non-prescribed medicines. Thirdly, the investigator identified the frequency and dosages of herbal products taken by each subject. Frequency included either continual use or on an as needed basis.

Question 4: What sources did women 65 and over use to obtain information about the use of herbal products?

To identify the source of information related to herbal products used by women 65 years and over, the participant was asked where she obtained information about

the herbal products that she was taking. Data related to health insurance status and primary health care provider were collected to identify a possible relationship between types of providers or insurance status and the use of herbal products. Data were collected to determine if the primary physician or other health care provider was aware of her use of herbal products.

Data Analysis

Descriptive statistics were performed to identify the demographic characteristics of the participants, number of medications used, number of herbal medications used, sources of information and reasons for taking herbal medications. Analysis of frequency was used to address each research question. The student t-test and Chi-Square test were used to determine if differences existed between older women who used herbal products and those who did not use herbal products.

CHAPTER IV RESULTS

This chapter includes a description of the research design, sample, demographic characteristics, and health related characteristics of the sample. Also included in this chapter are the results of the statistical analyses of the data corresponding to the research hypotheses and research questions.

Research Design

This research utilized a cross-sectional and descriptive design to examine the prevalence of herbal product use, types of herbal products used by the subjects, and to identify the reasons herbal products were used among women aged 65 and over. The investigator used a random selection process to facilitate the selection of two groups of subjects - those who used herbal products and those who did not use herbal products.

Sample

A random sample of women who were 65 years of age and over residing in a North Central Florida county was selected for this study. A total of 8,344 women who were

registered at the Florida Division of Drivers License, were identified as eligible sample by the State Department of Highway Safety and Motor Vehicles. To obtain a sample size of 84 subjects, three times this number or 252 possible subjects were randomly selected from the 8,344 women (see Table 4.1). Letters were mailed to the 252 possible subjects describing the research purpose and requesting the return of an enclosed postcard to schedule an interview. From this mailing, 16 letters were undeliverable and 101 (40.1%) persons responded. Of the 101 respondents who returned the postcards, 53 subjects completed interviews; 29 respondents declined participation; and 19 did not meet inclusion criteria. Thirty-one additional subjects were needed to attain the desired sample size.

An additional group of 150 people was selected for the second mailing to add the needed 31 subjects. Random sampling was repeated from a list of 8,344 persons, excluding the 252 names of the first selection. From the second mailing, 12 letters were undeliverable and 64 (42.7%) persons responded. Of the 64 respondents, 33 subjects completed interviews; 22 respondents declined participation; and nine did not meet inclusion criteria.

In summary, 402 letters were mailed; 28 of the 402 letters were undeliverable, leaving 374 potential subjects.

Of 374 potential subjects, 165 (44.1%) responded. Of the total 165 respondents, 86 subjects were completed interview (52%), 51 declined an interview (31%), and 28 did not meet inclusion criteria (17%). Reasons for exclusion were (a) five subjects had severe health problems, making an interview impossible; (b) three subjects resided in nursing homes or other types of assisted living facilities; (c) 12 subjects resided out of the county at the time of the interview; (d) six subjects were deceased; and (e) two subjects were unable to be contacted for the interview. Of the 86 subjects who completed the interview, 39 used herbal products and were assigned to group one and 47 did not use herbal products and were assigned to group two.

Table 4.1
Frequency Distribution of Total Sample

Number	1 st mailing	2 nd mailing	Total
letters mailed	252	150	402
Undeliverable	16	12	28
Excluded respondents	19	9	28
Non-Respondents	135	74	209
Declined Interview	29	22	51
Interview completed	53	33	86

Demographic Characteristics of the Sample

The mean age of the sample was 74.9 years with a standard deviation of 5.55 (range 65 - 90) (see Table 4.2). The mean age of the 39 subjects of group one who used herbal products was 75.4 years with a standard deviation of 5.80 (range 65 - 90). The mean age of the 47 subjects of group two who did not use herbal products was 74.4 years with a standard deviation of 5.37 (range 65 - 87).

Table 4.2
Age of Herbal Users, Non-Users, and Total Sample

Age	Herbal Users (n=39)	Non-Users (n=47)	Total Sample (N=86)
Mean years (\pm SD)	75.4 (\pm 5.80)	74.4 (\pm 5.37)	74.9 (\pm 5.55)
Group (years)	N (%)	N (%)	N (%)
65 - 74	17 (43.6)	24 (51.1)	41 (47.7)
75 - 84	18 (46.2)	20 (42.6)	38 (44.2)
85 and over	4 (10.2)	3 (6.3)	7 (8.1)
Total Number	39 (100.0)	47 (100.0)	86 (100.0)

Of the total group of subjects, 41 (47.7%) were married, 37 (43.0%) were widowed, and eight (9.3%) were divorced (see Table 4.3). From the 39 herbal users in the group one, 14 (35.9%) were married; 21 (53.8%) were widowed; and four (10.3%) were divorced. Among the 47 non-users in the group two, 27 (57.5%) were married; 16 (34.0%) were widowed; and four (8.5%) were divorced.

The sample consisted of 85 (98.8%) White Americans and one (1.2%) Black American. No other race was reported. The one Black American was an herbal product user and was placed in group one.

Among the total sample, 27 (31.4%) had some college education; 22 (25.6%) reported graduate level education after completion of college; 21 (24.4%) were high school graduates; 13 (15.1%) had college degrees; and three subjects had less than high school education. Of the 39 herbal product users in group one, three (7.7%) subjects had less than high school education; nine (23.1%) subjects finished high school; 12 (30.8%) had some college education; five (12.8%) subjects were college graduates; and 10 (25.6%) subjects had graduate level education after completion of college. Among the 47 subjects in group two, no one had less than a high school education; 12 (25.5%) completed high school; 15 (31.9%) had some college education; eight (17.0%) were college graduates; and 12 (25.5%) had graduate level education after completion of college.

Annual household income was categorized into four groups: less than \$ 20,000, \$20,000 - \$34,999, \$35,000 - \$49,999, \$50,000 or more. Seventy-nine (91.9%) subjects responded while seven (8.1%) declined to answer the

question related to income. Eighteen (22.8%) subjects reported their income to be less than \$20,000; 23 (29.1%) reported incomes of \$20,000 - \$34,999; 18 (22.8%) reported incomes of \$35,000 - \$ 49,999; and 20 (25.3%) reported their income level to be \$50,000 or more per year. Of the 39 herbal product users in group one, household income of eight (23.5%) subjects was less than \$20,000; 12 (35.3%) reported their income to be between \$20,000 and \$34,999; seven (20.6%) reported their income to be between \$35,000 and \$49,999; and seven (20.6%) reported incomes of \$50,000 or more per year. Among 47 non-users in group two, annual household income of 10 (22.2%) subjects was less than \$20,000; 11 (24.4%) subjects were between \$20,000 and \$34,999; 11 (24.4%) reported their income to be between \$35,000 and \$49,999; and 13 (28.9%) reported an income of \$50,000 or greater.

With regards to religious preference, Protestant was the most common religion (58, 67.4%) followed by Catholic (11, 12.8%). Three (3.5%) subjects practiced the Jewish religion; six (7.0%) reported other types of religion; and eight (9.3%) claimed no religious preference. Protestant was main religious preference in both herbal product users (26, 66.7%) and non-users (32, 68.1%).

Seventy-nine (92.9%) subjects had Medicare and supplemental insurance; three (3.5%) reported Medicare as their only insurance; two (2.3%) claimed Medicare and Medicaid; one (1.2%) had only Medicaid; and one (1.2%) had only private insurance. Of 39 the herbal product users, 35 (89.7%) had Medicare and supplemental insurance; one (2.6%) had Medicare only; two (5.1%) reported Medicare and Medicaid; one (2.6%) had private insurance. Among 47 non-users of group two, 44 (93.6%) subjects claimed Medicare and supplemental insurance; two (4.3%) had Medicare only; and one (2.1%) had Medicaid only. The summary of demographic characteristics including marital status, ethnicity, education, annual household income, religion, and insurance status for the total sample, for the group of herbal users, and for the group of non-herbal users is illustrated in Table 4.3.

Table 4.3
Demographic Characteristics of the Total Sample, Herbal Product Users, and Non-users

Characteristics	Herbal Users (n=39)	Non-Users (n=47)	Total Sample (N=86)	
Marital Status	N (%)	N (%)	N (%)	NS
Married	14 (35.9)	27 (57.5)	41 (47.7)	
Widowed	21 (53.8)	16 (34.0)	37 (43.0)	
Divorced	4 (10.3)	4 (8.5)	8 (9.3)	
Never Married	0 (0.0)	0 (0.0)	0 (0.0)	

Table 4.3. (continued)

Characteristics	Herbal Users (n=39)	Non-Users (n=47)	Total Sample (N=86)	
Ethnicity				NS
White American	38 (97.4)	47 (100)	85 (98.8)	
African American	1 (2.6)	0 (0.0)	1 (1.2)	
Hispanic-nonwhite	0 (0.0)	0 (0.0)	0 (0.0)	
Other	0 (0.0)	0 (0.0)	0 (0.0)	
Education				NS
< High School	3 (7.7)	0 (0.0)	3 (3.5)	
=High School	9 (23.1)	12 (25.5)	21 (24.4)	
<College Graduate	12 (30.8)	15 (31.9)	27 (31.4)	
=College Graduate	5 (12.8)	8 (17.0)	13 (15.1)	
≥ Graduate School	10 (25.6)	12 (25.5)	22 (25.6)	
Annual Income				NS
< \$20,000	8 (23.5)	10 (22.2)	18 (22.8)	
\$20,000- \$34,999	12 (35.3)	11 (24.4)	23 (29.1)	
\$35,000 - \$49,999	7 (20.6)	11 (24.4)	18 (22.8)	
≥ 50,000	7 (20.6)	13 (28.9)	20 (25.3)	
Missing Data	5 (12.8)	2 (4.3)	7 (8.1)	
Religion				NS
Protestant	26 (66.7)	32 (68.1)	58 (67.4)	
Catholic	4 (10.3)	7 (14.9)	11 (12.8)	
Jewish	1 (2.6)	2 (4.3)	3 (3.5)	
Other	4 (10.3)	2 (4.3)	6 (7.0)	
None	4 (10.3)	4 (8.5)	8 (9.3)	
Insurance				NS
Medicare & Supplement	35 (89.7)	44 (93.6)	79 (92.9)	
Medicare only	1 (2.6)	2 (4.3)	3 (3.5)	
Medicare & Medicaid	2 (5.1)	0 (0.0)	2 (2.3)	
Medicaid only	0 (0.0)	1 (2.1)	1 (1.2)	
Private Ins. Only	1 (2.6)	0 (0.0)	1 (1.2)	

NS = Statistically no significant difference between the group of herbal-product users and the group of non-users ($p = 0.05$)

Research Hypotheses

Research Hypothesis One

The first hypothesis stated that there was a difference in demographic characteristics of women 65 years

or over between the group of herbal product users and the group of non-users. To test the hypothesis, demographic characteristics including age, education levels, marital status, annual household income, and religious preference, were compared between the two groups. Ethnicity was not compared because all subjects except one Black American were identified as White Americans. Insurance status was not compared between the two groups since the total sample had some type of insurance and the large majority had Medicare (98%).

The research hypothesis one was not supported. The t-test was performed to test differences in age between the two groups and no significant difference in mean age was found between the two groups (\bar{t} = 0.76, p = 0.45). The two groups were homogeneous with regard to marital status (χ^2 = 4.089, p = 0.129). There was no significant difference in education between the group of herbal users and the group of non-users (χ^2 = 3.926, p = 0.416). There were no significant differences in annual household income (χ^2 = 3.265, p = 0.514) and in religious preference (χ^2 = 1.709, p = 0.789) between the two groups. In summary, the two groups were not significantly different in demographic characteristics

including age, marital status, education, annual household income, and religious preference.

Research Hypothesis Two

The second hypothesis stated that there was a difference in health-related characteristics between the group of herbal product users and that of non-herbal users. The health-related characteristics included perception of own health status, number of health care providers who were visited, types of health-related problems and perception of its seriousness, number of health problems, and number of prescribed and non-prescribed medicines.

Perception of health status and health care providers.

Perceptions of health including overall health, physical health, and emotional health were measured by a visual scale that ranged from one to five. Five on the visual scale represented excellent health; and one on the visual scale represented poor health (see Appendix A). Overall health was rated five on the visual scale by 25 (29.1%) of the total sample; four on the visual scale by 39 (45.4%); three on the visual scale by 20 (23.3%); and two on the visual scale by two (2.3%). No subject gave a rating of one on the visual scale (see Table 4.4). Among 39 herbal product users in group one, no subject gave a rating of either one or two suggesting poor overall health; nine

(23.1%) subjects rated three on the visual scale; 16 (41.0%) subjects rated four; and 14 (35.9%) subjects rated five suggesting excellent overall health. Among 47 non-herbal product users in group two, no subject gave a rating of one; two (4.3%) subjects rated two on the visual scale; 11 (23.4%) subjects rated three; 23 (48.9%) subjects rated four; and 11 (23.4%) subjects rated five. There was no significant difference in perception of overall health between the two groups ($\chi^2 = 3.100$, $p = 0.378$).

Table 4.4

Perceived Overall Health by Herbal-Users, Non-Users, and Total Sample

Visual Scale (1-5)	Herbal Users (n=39)	Non-Users (n=47)	Total Sample (N=86)
1 (Poor)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	0 (0.0%)	2 (4.3%)	2 (2.3%)
3	9 (23.1%)	11 (23.4%)	20 (23.3%)
4	16 (41.0%)	23 (48.9%)	39 (45.4%)
5 (Excellent)	14 (35.9%)	11 (23.4%)	25 (29.1%)
Total	39 (100.0%)	47 (100.0%)	86 (100.0%)

Physical health was rated two on the visual scale by three (3.5%) subjects; three on the visual scale by 21 (24.4%) subjects; four on the visual scale by 41 (47.7%) subjects; and five on the visual scale by 21 (24.4%) subjects (see Table 4.5).

Table 4.5
Perceived Physical Health by Herbal-Users, Non-Users, and
Total Sample

Visual Scale (1-5)	Herbal Users (n=39)	Non-Users (n=47)	Total Sample (N=86)
1 (Poor)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	1 (2.6%)	2 (4.3%)	3 (3.5%)
3	10 (25.6%)	11 (23.4%)	21 (24.4%)
4	18 (46.2%)	23 (48.9%)	41 (47.7%)
5 (Excellent)	10 (25.6%)	11 (23.4%)	21 (24.4%)
Total	39 (100.0 %)	47 (100.0%)	86 (100.0%)

Among subjects in group one, no subject gave a rating of one suggesting poor physical health; one (2.6%) subject rated two; 10 (25.6%) subjects rated three; 18 (46.2%) subjects rated four; and 10 (25.6%) subjects rated five suggesting excellent physical health. Among 47 non-herbal product users in group two, no subject gave a rating of one; two (4.3%) subjects rated two; 11 (23.4%) subjects rated three; 23 (48.9%) subjects rated four; and 11 (23.4%) subjects rated five. There were no significant differences in perception of physical health between the two groups ($\chi^2 = 0.297$, $p = 0.961$).

Emotional health was rated two on the visual scale by one (1.2%) subject; rated three on the visual scale by six (7.0%); rated four by 27 (31.4%); and five or excellent on the visual scale by 52 (60.4%) subjects (see Table 4.6).

Table 4.6
Perceived Emotional Health by Herbal-Users, Non-Users, and
Total Sample

Visual Scale (1-5)	Herbal Users (n=39)	Non-Users (n=47)	Total Sample (N=86)
1 (Poor)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	1 (2.6%)	0 (0.0%)	1 (1.2%)
3	2 (5.1%)	4 (8.5%)	6 (7.0%)
4	10 (25.6%)	17 (36.2%)	27 (31.4%)
5 (Excellent)	26 (66.7%)	26 (55.3%)	52 (60.4%)
Total	39 (100.0%)	47 (100.0%)	86 (100.0%)

Among subjects in group one, no subject gave a rating of one suggesting poor emotional health status; one (2.6%) subject rated two; two (5.1%) subjects rated three; 10 (25.6%) subjects rated four; and 26 (66.7%) subjects rated five suggesting excellent emotional health. Among subjects in group two, no subject gave a rating of either one or two on the emotional health status; four (8.5%) subjects rated three; 17 (36.2%) subjects rated four; and 26 (55.3%) subjects rated five, which represents excellent emotional health. There was no significant difference in perceived emotional health between the group of herbal product users and that of non-users ($\chi^2 = 2.761$, $p = 0.430$).

A large number of the total sample visited at least one health care provider in the past 12 months. Eighty-three subjects (96.5%) visited at least one health care provider in the past 12 months. Only three subjects (3.5%)

had not visited any type of health care provider within the past 12 months. Two of three subjects who did not visit any health care provider were herbal product users.

The mean number of health care providers reported by the sample was 2.56 (SD = 1.38, range 0 - 7). The average number of health care providers the herbal product users reported was 2.31 (SD = 1.42, range 0 - 7) in comparison to 2.77 health care providers (SD = 1.32, range 0 - 6) reported by non-users. There was no significant difference in number of health care providers that the sample had between the group of herbal product users and the group of non-users ($t = 1.549$, $p = 0.063$). Internal medicine was the most frequently visited specialty reported by 55 (64%) subjects, and the second most frequently visited was family practice reported by 35 (40.7%) subjects.

Types and seriousness of health-related problems.

Among 86 subjects of the total sample, 85 (98.8%) reported at least one or more problems from the 23 categories of health-related problems (see Table 4.7). Of the health-related problems reported, arthritis (55.8%), allergies (48.8%), and fatigue (45.3%) were identified as major health-related problems by about half of the total sample followed by back problems (39.5%), digestive problems (34.9%), and urinary problems (32.6%). Other

health problems commonly reported by subjects were skin problems (29.1%), heart problems (27.9%), high blood pressure (26.7%), and memory problems (22.1%). The average number of health-related problems reported by each subject was 5.8 problems. The group of herbal users (39 subjects) identified an average of 6.1 health-related problems while an average of 5.5 health-related problems was reported by the group of non-users (47 subjects).

Each health-related problem in 23 different areas was compared between the group of herbal users and that of non-users. There was significant difference in memory problem between the two groups ($\chi^2 = 5.238$, $p = 0.022$). Thirteen subjects in the group of herbal product users reported memory problems while six subjects of the counter part reported memory problems. Differences were not found in other areas of health-related problems between the two groups (see Table 4.7).

Table 4.7
Types of Health-Related Problems (N=86)

Number and Types of Problems	Herbal Product users	Non-Users	Total Users N (%)	p
No. of Health Problems				
\bar{X}	6.08	5.53	5.78	
SD	3.13	3.15	3.13	
Range	(1-14)	(0-12)	(0 - 14)	
Arthritis	23	25	48 (55.8)	NS

Table 4.7 (continued)

Number and Types of Problems	Herbal Product users	Non-Users	Total Users N (%)	p
Allergies	20	22	42 (48.8)	NS
Fatigue (low energy)	17	22	39 (45.3)	NS
Back problems	20	14	34 (39.5)	NS
Digestive Problems	14	16	30 (34.9)	NS
Urinary problems	13	15	28 (32.6)	NS
Skin problems	13	12	25 (29.1)	NS
Heart problems	9	15	24 (27.9)	NS
High Blood Pressure	8	15	23 (26.7)	NS
Dizziness	10	9	19 (22.1)	NS
Memory problems	13	6	19 (22.1)	$\underline{P}=0.02$
Anxiety	6	9	15 (17.7)	NS
Blood & Circulatory problems	7	7	14 (16.3)	NS
Chronic Pain	9	5	14 (16.3)	NS
Cold & Flu	6	8	14 (16.3)	NS
Obesity	8	4	12 (14.0)	NS
Headache	4	7	11 (12.8)	NS
Cancer	2	7	9 (10.5)	NS
Diabetes	1	7	8 (9.3)	NS
Depression	4	3	7 (8.1)	NS
Lung problems	3	4	7 (8.1)	NS
Gynecological problems	1	0	1 (1.2)	NS
Others	26	28	54 (63.8)	NS

Notes: NS = no significant difference between the group of herbal product users and the group of non-users ($p = 0.05$)

Each subject was asked about the seriousness of identified health-related problems in her daily living by

using a visual scale which ranged from one to five. One represented no interruption in daily living from the health problem, while five represented an extremely serious interruption in daily living from the identified health-related problem. Seriousness of each health-related problem was compared between the two groups in all 23 areas. The two groups were homogeneous with respect to seriousness of health-related problems in all areas except obesity. The group of herbal product users and the group of non-users were not homogeneous in regards to seriousness of obesity (Fisher's Exact 2-Tail Test, $p = 0.0222$) although the two groups were homogeneous with regards to obesity as a health-related problem ($\chi^2=2.557$, $p=0.129$).

Of all subjects who reported health-related problems, the majority indicated that the seriousness of health problems in their daily living was three, two or one on the visual scale. The seriousness of memory problems in interfering with everyday life was not significantly different between the group of herbal product users and the group of non-users ($\chi^2=2.219$, $p=0.708$) although the two groups were different in the frequency of memory as a health-related problem.

Use of prescribed and non-prescribed medicines.

The use of prescribed medicines was reported by 75 (87.2%) of the total sample. The average number of prescribed medicines used by the total sample was 3.20 medicines (SD = 2.40; range 0 - 10); herbal product users reported a mean of 3.00 medicines (SD = 2.21; range 0 - 8); and non-users reported mean of 3.36 medicines (SD = 2.56; range 0 - 10). There was no significant difference in the use of prescribed medicines between the group of herbal product users and that of non-users ($t=1.75$, $p=0.08$).

All but one of the total sample (98.8%) reported the use of non-prescribed medicines. The mean number of non-prescribed medicines used by the total sample was 3.79 medicines (SD = 1.90; range 0 - 9); herbal product users reported a mean of 4.18 medicines (SD = 1.94; range 1 - 9); and non-users reported a mean of 3.47 medicines (SD = 1.82; range 0 to 8).

Of the non-prescribed medicines used by sample, many of them were taken on a regular basis. The most frequently used non-prescribed medicines taken regularly were multivitamin, calcium, vitamin E, vitamin C, and aspirin (see Table 4.8). More than one-third of the total sample was using at least one of these five non-prescribed medicines. Of the forty-eight subjects (55.8%) in the total

sample who used multivitamins, 22 (56.4%) were herbal product users and 26 (55.3%) were non-herbal product users. Calcium was the second most frequently used non-prescription medicine among the sample. Forty-seven (54.7%) subjects in the total sample were taking calcium including 20 (51.3%) were herbal-product users and 27 (57.4%) were non-users. Forty-one subjects (47.1%) in the total sample were taking Vitamin E; 22 (56.4%) subjects from the herbal-product users and 19 (40.4%) from the non-users. Among 29 subjects (33.3%) from the total sample who used vitamin C, 18 (46.2%) were herbal-product users; and 11 (23.4%) were non-users. Aspirin was regularly used by 27 subjects (31.4%) in the total sample. Eleven subjects (28.2%) were herbal-product users and 16 (34.0%) were non-users.

Table 4.8
Frequently Used Non-prescribed Medicines Taken Regularly

Non-prescribed medicines	Herbal-Product Users (n=39)	Non-Users (n=47)	Total (N=86)
	No. (%)	No. (%)	No. (%)
Multivitamin	22 (56.4)	26 (55.3)	48 (55.8)
Calcium	20 (51.3)	27 (57.4)	47 (54.7)
Vitamin E	22 (56.4)	19 (40.4)	41 (47.1)
Vitamin C	18 (46.2)	11 (23.4)	29 (33.3)
Aspirin	11 (28.2)	16 (34.0)	27 (31.4)

There was no significant difference in the number of non-prescribed medicines used between the group of herbal product users and non-users ($t=0.69$, $p=0.49$). In summary, the average number of medicines including both prescribed and non-prescribed medicines for each subject of the total sample was 6.99 medicines (SD = 2.85; range 1 - 17). The average number of total medicines used by herbal product users was 7.18 medicines (SD = 2.80; range 1 - 17), while the non-herbal product user group used 6.83 medicines (SD = 2.9; range 2 - 15). There was no significant difference in the use of total number of medicines between the two groups ($t=0.56$, $p=0.57$). The summary of the use of prescribed, non-prescribed, and total number of medicines used by sample is illustrated in Table 4.9.

Table 4.9

Use of Prescribed, Non-prescribed Medicines by Sample
(N=86)

Medicines (n)	Herbal Users (n=39)		Non-Users (n=47)		Total Sample (N=86)		
	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	
	(Min-Max)		(Min-Max)		(Min-Max)		
Total Medicines	7.18	±2.80 (1 - 17)	6.83	±2.91 (2 - 15)	6.99	±2.85 (1 - 17)	NS
Prescribed Medicines	3.00	±2.21 (0 - 8)	3.36	±2.56 (0 - 10)	3.20	±2.40 (0 - 10)	
Non-prescribed Medicines	4.18	±1.94 (1 - 9)	3.47	±1.82 (0 - 8)	3.79	±1.90 (0 - 9)	NS

NS = Statistically not significant between the group of herbal product users and non-users ($p = 0.05$)

Description of the Research Questions

Research Question One

The first research question was stated as, what is the prevalence of use of herbal products among women 65 years and older. Of the total sample of 86 subjects, 39 (45.3%) reported using herbal products in the past 12 months. A total of 98 herbal products were used by the 39 subjects, which averaged 2.51 herbal products per subject (SD = 2.16; range 1 - 11). The three most commonly used herbal products were Ginkgo Biloba or Ginkgo Biloba with other combinations (12 subjects), garlic tablets and cloves (11 subjects), and Glucosamine with Chondroitin (8 subjects). Ninety-two herbal products (93.9%) were taken orally, while six (6.1%) herbal products were used externally. About three-quarters (76%) of the total number of herbal products were in a ready-to-take form such as tablets, capsules, or liquid preparations; and 24% of the herbal products required some preparation by the subjects. The types of herbal products used by the subjects are illustrated in Table 4.10.

Table 4.10

Types of Herbal Products Used by Subjects

Name (n)	Name (n)
Ginkgo or Ginkgo combinations (12)	Paprika Powder (1)
Garlic (11)	Hot Spicy Pepper (1)
Glucosamine w/ chondroitin (8)	Shark Cartilage (2)
Aloe (5)	Barley Green (1)
Herbal Tea (Parsley, Basil, Peppermint tea) (4)	Grapefruit Seeds Extract (1)
Echinacea (4)	Anica (1)
Ginger (4)	MSM (1)
St. Johns Wort (3)	Bakuchi Oil (1)
Vinegar w/Honey (3)	Triphala Tea (1)
Primrose (3)	Grape Seeds Extract (1)
G.H.3 (2)	Spiru-Tein (1)
Ginseng (2)	Co Q-10 (1)
Green Tea (2)	Acidophilus (1)
Selenium (2)	Cod Liver Oil w/ Whole Milk
Flax Oil Complex or Flax Tea (2)	Soy Bean Oil Beta Carotene (1)
Pure Cranberry Juice (1)	Lecithin Capsules (1)
Pantothenic Acid (1)	Provex (1)
Melatonin (1)	Seven Forests (1)
Papaya Capsules (1)	Eight Prunes (1)
Manchurian Mushroom Tea (1)	Chromium Picolinate (1)
Sesame Oil w/ five whole cloves (1)	Liver Flush (Mix of Olive Oil, Lime Juice, Apple Cider Vinegar, & Red Pepper) (1)
Stevia Liquid Extract (1)	Calms Forte (1)
Cayenne Pepper Capsules (1)	Ghee w/ boiled Butter (1)
Nature's Tea (Colon Cleanser) (1)	Brewer's Yeast w/ Orange Juice, or Milk and Honey (1)

Research Question Two

The second question was stated as what is the purpose for taking herbal products and/or herbs by women 65 years and over. Do older women take herbal products more for prevention or for treatment of symptoms?

Of the persons taking herbals, 16 (41%) reported using herbal products to maintain health or to prevent possible health problems. Nine subjects (23%) used herbal products for treatment of health problems. Fourteen subjects (36%) used herbal products both to prevent and to treat health problems (see Table 4.11). Of the 98 herbal products used by the subjects, 55 (56.1%) products were used to prevent health problems or to maintain health, while 43 (43.9%) of the herbal products were used to treat health problems. The three major purposes for using herbal products other than prevention were to improve memory, to treat arthritis, and to remedy digestive problems.

Table 4.11
Purposes of Using Herbal Products by Subjects and by Number of Herbal Products

Reasons to take herbal products	Subjects (n=39)	No. of Herbal Products (n=98)
To treat health problems	9 (23%)	43 (43.9%)
To maintain health or prevent health problems	16 (41%)	55 (56.1%)
For both treatment and prevention purposes	14 (36%)	N/A
Total	39 (100%)	98 (100%)

The perceived benefit of taking the herbal products was also identified. About one-half of the herbal products (47.9%) were perceived by subjects to be somewhat effective or very effective while the effectiveness of 40.6% of herbal products was unknown. Only one subject reported any side effect from taking the herbal products. This subject reported diarrhea as a side effect after taking gingerroot tablets for a period of three months.

Research Question Three

The research question was stated as what is the frequency of use of herbal products by women aged 65 and over. Do women who use herbal products use them continuously over time or on an as needed basis? Do women who use herbal products use them alone or in combination with prescribed and /or non-prescribed medicines?

Thirty-nine subjects in group one used a total of 98 herbal products with a mean of 2.51 herbal products per subject ($SD = 2.16$, range 1 - 11). Subjects reported that 85.4% of the herbal products used were taken on a continual basis. These products had been used for a mean of 34.8 months with a standard deviation of 92.3 months (range one-half month - 600 months). Fourteen herbal products (14.6%) were used when symptoms occurred. Of the 98 total herbal

products used by the subjects, 14 (14.3%) were used in combination with prescribed or non-prescribed medicines to treat health problems. Twenty-nine herbal products (29.6%) were used alone for treating health problems reported by the subjects. Fifty-five herbal products (56.1%) were taken for the purpose of maintaining health and/or preventing possible health problems. Data indicated that, of 41 herbal products used for treating health problems, 27 were taken on continual basis, while 14 of 49 herbal products were used only when symptoms occurred.

Research Question Four

The research question was stated as what sources do women 65 years and over use to obtain information about herbal products? The primary sources used by the subjects to obtain information related to the use of herbal products were as follows: (a) 22 subjects used books or magazines; (b) 19 subjects were informed by family members; (c) 16 subjects used friends and neighbors; and (d) 14 subjects used television, radio or newspapers. Other sources used to gain information were alternative health care practitioners, health care providers, health food stores, and newsletters. No subject reported obtaining information from the Internet.

Other Findings

Ninety-six (98%) of the total of 98 herbal products used by the sample were purchased with self-payment by subjects. Two herbal products (2%) were obtained free from relatives of subjects. Health insurance companies did not pay for any herbal products used by subjects.

Among 98 herbal products reported by 39 subjects, 71 herbal products (72.4%) were not reported to the health care providers of the subjects, while 27 herbal products (27.6%) were reported to the health care providers. Of 39 herbal product users, 16 subjects (41%) reported their use of herbal products to their health care providers. Although 16 subjects who reported their use of herbal products, not all herbal products used by these 16 subjects were reported to their health care provider, which indicated only part of the herbal products they used were reported. While 48 herbal products from a total of 98 herbal products consumed by 16 subjects who reported their use of herbal products, only 27 of 48 herbal products were reported to their health care providers. Health care providers who were the most frequently informed of the use of herbal products were internists by eight subjects and family practices by four subjects.

In summary, the research findings did not show differences in demographic characteristics and in the characteristics of health status between the group of herbal product users and non-users. However, herbal product users reported significantly more memory problems than the group of non-users although perceived seriousness of memory problems in daily living was not significantly different between the two groups.

Research results indicated that many older women in the community used herbal products for the purposes of preventing possible health problems and for promoting their current health status as well as for treating health problems. Major resources for obtaining the information about herbal products were media, mainly magazines and newsletters. Many herbal products taken by subjects were not reported to health care providers and no payment for herbal products was made by health insurance.

CHAPTER V

DISCUSSION AND RECOMMENDATIONS

The purpose of this research was to explore the use of herbal products for medicinal purposes and to compare differences in demographic characteristics and in characteristics of health status between the group of herbal product users and the group of non-users among community-dwelling women aged 65 years and over.

Data were examined from a random sample of women aged 65 years and over residing independently in a North Central Florida county. This chapter presents a discussion of the findings and the conclusions of the study according to the hypotheses and research questions. This chapter also presents recommendations for future research and implications for nursing practice.

Discussion and Conclusions

The data indicated that the group of herbal product users and the group of non-users were homogeneous in demographic characteristics including age, marital status, ethnicity, level of education, level of income, religious

preference and insurance status. With one exception, the groups were also homogeneous in characteristics related to their health status. There was a statistically significant difference in the reported incidence of memory problems between the two groups, with the group using herbal products reporting a higher incidence.

Demographic Characteristics of the Sample

According to the U.S. Bureau of the Census, residents who are 65 years and over comprise 9.2% of the total resident population in this North Central Florida county (U.S. Bureau of the Census: 1990-US Census Data C90STF1A Summary Level: State-County, <http://www.census.gov/cgi-bin/datamap/cnty?12=001>). The ratio of females to males in the 65 years and over group in this county was 60.9% and 39.1% respectively (see Table 5.1).

Table 5.1

Frequencies and Percentages of Females and Males Aged 65 and Over in a North Central Florida County (N=16,765)*

Gender	Frequency	Percentage
Female	10,203	60.9
Male	6,562	39.1

* 1990 Census by the U.S. Bureau of the Census

Females, who were 65 years and over in this county were comprised of 81.2% white; 17.0% black; 1.3% Hispanic origin; 0.3% Asian or Pacific Islander; and less than 0.1%

American Indian, Eskimo, or Aleut (U.S. Bureau of Census: 1990-US Census Data C90STF3A Summary Level: State-County, <http://venus.census.gov/cdrom/lookup/908144154>) (see Table 5.2).

Table 5.2

Summary of Races among Females aged 65 and over (N=10,203)*

Race	Frequency	Percent
White	8,287	81.2
Black	1,738	17.0
Hispanic origin	135	1.3
Asian or Pacific Islander	34	0.3
American Indian, Eskimo, or Aleut	9	0.1

Race was not identified on the list of potential subjects from the State Department of Highway Safety and Motor Vehicles. Therefore, it was not possible to know the race distribution of the sample. In spite of a random sampling procedure, from 86 subjects, 85 (98.8%) were White Americans and one (1.2%) was African American. The racial distribution for non-respondents for persons who declined interviews or persons who were excluded from the study was unknown. There appears to be an under-representation of African Americans and other minorities in this sample. The reasons for this under representation of African Americans and other minorities are unknown. The possible reasons may be that African Americans 65 years and over are less likely

than White Americans to (a) have a drivers license; (b) respond to requests for participation in research; and (c) to agree to an interview.

The level of education of the sample was slightly higher than the average educational level of the County studied. According to the data of USA counties 1996 provided by the U.S. Bureau of the Census, the percentage of college graduates was 34.6% among persons 25 years and over in 1990 in this North Central Florida county (U.S. Bureau of the Census, USA Counties 1996). In the study sample, 37.7% were college graduates or postgraduates, 31.4% reported some years of college education, and 24.4% graduated from high school. The educational level of this sample is consistent with other studies which related to the use of alternative medicines (Eisenberg et al., 1993; Eliason, Kruger, Mark, & Rasmann, 1997). The results of this study showed that there was no significant difference in the level of education between the group of herbal product users and the group of non-users.

In conclusion, there was no difference between subjects who used herbal products and those who did not use herbal products related to demographic characteristics including marital status, level of education, annual income, religious preference, and insurance status.

Findings related to race were inconclusive due to a small sample size of African Americans.

Characteristics of Health Status

Among the sample of 86 subjects, 83 (96.5%) subjects visited at least one type of health care provider in the past 12 months and averaged 2.56 different types of health care providers (SD = 1.38, range 0 - 7). Health care providers were aware of only about one-fourth of the total number of herbal products used, which meant that three-quarters of herbal products consumed by older women were unknown to their health care providers. Even though subjects identified and visited their health care providers, they did not share information related to the use of herbal products.

Perception of health was examined by asking subjects about their own perception of overall health, physical health, and emotional health. Most subjects perceived that their overall health, physical health, and emotional health were good or excellent for their age, although the sample reported an average of 5.8 health-related problems and reported taking an average of more than three prescribed medicines each. Most subjects considered their health-related problems not extremely serious, not serious enough

to interrupt daily activities, and relatively well controlled with medications.

All of the subjects in this study were taking at least one prescribed or non-prescribed medicine. The number of medications reported by these subjects (a mean of 3.20 prescribed medicines, 3.79 non-prescribed medicines and combined 6.99 medicines) were within the range reported in previous studies. Reports of prescription drug use by community dwelling elders have ranged from averages of 1.5 to 6.1 medications; whereas, figures on non-prescription drug usage have ranged from 1.3 to 4.6 (Darnell, Murray, Martz, & Weinberger, 1986; Pollow, Stoller, Forster, & Duniho, 1994; Shimp, Ascione, Glazer, & Atwood, 1985). While vitamins and mineral products were considered as non-prescribed medicines in the present study, it is unclear if these products were considered as medications in the previous studies. The data from the present study suggest that 71 (82.6%) subjects from a total of 86 subjects practice a self-care regimen by using multiple vitamins and minerals to maintain their health.

Use of Herbal Products

Based on prior research, the use of herbal products ranges from three percent to 80%. Past studies have varied in geographical areas as well as age of subjects.

(Eisenberg et al., 1993; Frate et al., 1996; WHO, 1993).

The results of this study in a North Central Florida county indicated that 46% of community-dwelling women 65 years and over are users of herbal products. Both men and women 18 years and over were studied by Eisenberg and colleagues (1993), Frate and colleagues (1996), and WHO (1993) and the prevalence of use of herbal products from these samples were reported to be 3%, 70% and 80% respectively.

Although it is difficult to compare the results of these studies because of the different characteristics of the samples, data from the present study suggest that the use of herbal products among older women is common (almost one of two older women). The primary use of herbal products by this sample was for prevention and self-treatment. The use of herbal products for the purpose of prevention of health problems was more prevalent than the use of herbals for self-treatment among women in this study. Most of the herbal products (85.6%) were taken on a continual basis rather than as intermittent use.

The use of herbal products in this study was more likely to be a ready-made form for easy usage, such as tablets and caplets, rather than using parts of the original plant and further preparing the herb for use. The practice of taking a tablet or capsule is in synchrony with

the current U.S. societal attitude of a "quick fix." This sample was more likely to digest the herb internally rather than applying the herb externally.

The most commonly consumed herbal products in this study were Ginkgo Biloba or Ginkgo combinations, garlic, Glucosamine with Chondroitin, aloe, herbal teas, Echinacea, and ginger. Eliason and colleagues (1997) indicated that the most commonly used herbal products in their study were garlic, Ginseng, Ginkgo Biloba, Evening primrose oil, Echinacea, and Alfalfa. Frate and colleagues (1996) reported that lemon, aloe, castor, turpentine, tobacco, and garlic were the most frequently mentioned plant-derived medicines. According to Ernst (1998), the popular herbal products are Echinacea, Garlic, Goldenseal, Ginseng, Saw palmetto, aloe, Ma huang, and cranberry. The types of commonly used herbal products in this study were consistent with previous studies (Eliason et al., 1997; Ernst, 1998; Frate et al., 1996) identifying garlic, Ginkgo Biloba, aloe, and Echinacea as commonly consumed herbal products.

The group of herbal product users in the present study indicated that they identified more memory problems than the group of non-users; however, the group of herbal product users did not consider that memory problems affected their everyday living more seriously than

non-users. As a result, Ginkgo Biloba was the most frequently used herbal product by older women in this study. Ginkgo Biloba was used to maintain present memory status, to improve memory, or to prevent possible memory problems.

The results of this study indicated that a variety of herbal products was used for self-treatment and self-care based on self-diagnosis by older women. From the list of health problems (see Appendix A) identified by older women in this study, arthritis was the most frequently mentioned problem by both herbal product users and non-users. The subjects who used herbal products reported frequent use of Glucosamine with chondroitin for the treatment of arthritis. Many older women in this study were concerned about possible high blood pressure and heart problems and frequently used garlic to maintain their current health status and to prevent possible cardiovascular problems.

Information about herbal products was obtained mainly through media such as magazines, books, newsletters, and television. Other sources of herbal product information were commonly family members, friends, and neighbors. About half of the herbal products used by subjects were believed to be somewhat effective or very effective. The effectiveness of more than 40% of herbal products that

subjects used was not known. In spite of not recognizing an immediate benefit of using herbal products, reasons for using these herbal products continually were that they would not be harmful and the products would be beneficial to the person someday or someday.

Issues Related to Use of Herbal Products

It was apparent that many older women have used herbal products for their health care practice along with conventional medicines based on their own judgement about health and the herbal products. However, this study identified a few problems of using the herbal products in spite of their perceived benefit as natural products. The first identified problem related to the ingredients of the herbal product. When subjects informed the investigator of the herbal product they used, there was more than one ingredient contained in the product. The ingredients were written on the label in very small letters, which older adults find difficult to read. Therefore, subjects did not know exactly what ingredients were being consumed. Secondly, the investigator identified that subjects were inconsistent in the dose of herbals taken since the dosage varied between brands of the same herbal products. Thirdly, although it was claimed that some herbal products were safer than conventional medicines in clinical tests of the

safety of herbal products (Ernst, 1998), the herbal and drug interactions or herbal and herbal interactions are basically unknown. Therefore, there were potential risks for subjects who were taking herbal products in combination with conventional medicines for treating their problems.

Many health care providers did not ask their clients about the use of herbal products and, therefore, did not recognize the use of herbal products by their clients. As a result, it is possible for health care providers to make erroneous decisions in prescribing conventional medications to clients, if the knowledge of herbal product use by their clients is unknown.

Finally, although more than one-half of the herbal products was believed to be effective, persons using herbal products have little to no basis for judging effectiveness of the products. Subjects were not in sure of the effectiveness of approximately less than one-half of the herbal products used in this study and this was the major reason that some subjects discontinued use of the herbal product. Duration of use of herbal products showed a wide range of time the product was taken.

In summary, there are no requirements to demonstrate safety and efficacy through clinical testing or for use of herbal products. This lack of requirement does not negate

the importance of knowledge related to possible drug interactions associated with the use of herbal products.

Implication for Nursing and Recommendations

This study has important implications for nursing practice. With the knowledge that approximately 50% of women over 65 years of age use some form of herbal product, and the majority do not discuss this use of herbals with their health care providers, it behooves nurses to include questions about the use of herbal products as a routine part of their history taking process. This information should not only be obtained from women with chronic illnesses, but also from women who are preventive care.

Nurses need a better understanding of the herbal products that people use since they are often the first health care providers to interview individuals seeking medical assistance. It is believed that most nurses have minimal knowledge related to the use of herbal products. It is recommended that information about herbal products be included in nursing education curriculum and that continuing education programs be offered for practicing practitioners.

There are also implications for future research on the topic of the use of herbal products. Researchers need to examine the use of herbal products among different ethnic

groups, different age groups, and in different geographical settings. Further studies are needed to examine the possible interactions between herbal products and conventional medicines. Intervention or case-controlled studies could help to determine the effectiveness of the use of herbal products to maintain health, to prevent illness, or to treat specific disease conditions.

Little is known about the relationship between the use of herbal products and memory loss. Findings from this study suggest that there is a difference between persons with perceived memory problems who use herbal products and those who do not use herbals. Persons who use herbals are more likely to claim memory problems than those who do not use herbals. Alzheimer's Disease and related memory disorders are more common among older women than any other age or gender group. Also, there are few scientifically supported interventions for most memory disorders. Therefore, it is not surprising that older women are actively seeking help for this problem. Research needs to be done to replicate this finding. Also, researchers should identify the relationships between the use of herbal products and memory problems. For example, are persons with memory problems more likely to take herbal products than those without memory problems; or are persons who take

herbal products more likely to have memory problems than those who do not take herbals. As with any intervention, studies need to be done to validate the effectiveness of the intervention.

It appears that in the past, health care professionals have basically ignored the use of herbal products by their clients. Marketing through radio, television, and written media has greatly impacted the use of these products. The benefits versus risks of herbal use are unknown. Yet, as any product taken alone or in combination with conventional medicines, herbal products need to be examined for effectiveness, risks, and safety rather than to be left to the individual persons or the marketplace for the determination of these factors.

REFERENCES

- Ackerknecht, E. H. (1973). Therapeutics: From the primitives to the 20th century. New York: Hefner Press.
- Anderson, L. A. (1996). Concern regarding herbal toxicities: Case reports and counseling tips. The Annals of Pharmacotherapy, 30, 79-80.
- Boisset, M., & Fitzcharles, M. A. (1994). Alternative medicine use by rheumatology patients in a universal health care setting. The Journal of Rheumatology, 21, 148-152.
- Brown, J. S., & Marcy, S. A. (1991). The use of botanicals for health purposes by members of a prepaid health plan. Research in Nursing and Health, 14, 339-350.
- Brunton, S. A. (1984). Physicians as patient teachers. Western Journal of Medicine, 141, 855-860.
- Buchman, D. D. (1980). Herbal medicine. New York: Gramercy Publishing Co.
- Burg, M. A. (1996). Women's use of complementary medicine: Combining mainstream medicine with alternative practices. Journal of Florida Medical Association, 83, 482-488.
- Cassileth, B. R., & Chapman, C. C. (1996). Alternative and complementary therapies. Cancer, 77, 1026-1034.
- Chenitz, W. C., Salisbury, S., & Stone, J. T. (1990). Drug misuse and abuse in the elderly. Issues in Mental Health Nursing, 11, 1-16.

Chrischilles, E. A., Foley, D. J., Wallace, R. B., Lemke, J. H., Semla, T. P., Hanlon, J. T., Glynn, R. J., Ostfeld, A. M., & Guralnik, J. M. (1992). Use of medication by persons 65 and over: Data from the Established Populations for Epidemiologic Studies of the Elderly. Journal of Gerontology: Medical Sciences, 47, M137-M144.

Cobbs, E. L., & Ralapati, A. N. (1998). Health of older women. Medical Clinics of North America, 82 (1), 127-144.

Col, N., Fanale, J. E., & Kronholm, P. (1990). The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly. Archives of Internal Medicine, 150, 841-845.

Coleman, L. M., Fowler, L. L., & Williams, M. E. (1995). Use of unproven therapies by people with Alzheimer's disease. Journal of American Geriatrics Society, 43, 747-750.

Colt, H. G., & Shapiro, A. P. (1989). Drug-induced illness as a cause for admission to a community hospital. Journal of American Geriatrics Society, 37, 323-326.

Cramer, J. A., Mattson, R. H., Prevey, M. L. Scheyer, R. D., & Ouellette, V. L. (1989). How often is medication taken as prescribed?: A novel assessment technique. Journal of American Medical Association, 261, 3273-3277.

Cusack, B. J. (1989). Polypharmacy and clinical pharmacology. In J. Beck (Ed.), Geriatric review syllabus: A core curriculum in geriatric medicine (pp. 127-136). New York: American Geriatric Society.

Darnell, J.C., Murray, M. D., Martz, B. L., & Weinberger, M. (1986). Medication use by ambulatory elderly: An in-home survey. Journal of the American Geriatrics Society, 34, 1-4.

Delafuente, J. C. (1991). Perspectives on geriatric pharmacotherapy. Pharmacotherapy, 11, 222-224.

De Smet, P.A.G.M. (1995). Health risks of herbal remedies. Drug Safety, 13, 81-93.

Dietary Supplement Health and Education Act of 1994 (1994). Public Law 103-417, 103d Congress. Federal Food, Drug, and Cosmetic Act. 108 STAT.4325-108 STAT.4328.

Drew, A. K., & Myers, S. P. (1997). Safety issues in herbal medicine: Implications for the health professions. Medical Journal of Australia, 166, 538-541.

Eisenberg, D. M., Kessler, R. C., Forster, C., Norlock, F. E., Calkins, D. R., & Delbanco, T. L. (1993). Unconventional medicine in the United States: Prevalence, costs, and patterns of use. The New England Journal of Medicine, 328, 246-252.

Eliason, B. C., Kruger, J., Mark, D., & Rasmann, D. N. (1997). Dietary supplement users: Demographics, product use, and medical system interaction. Journal of American Board of Family Practice, 10, 265-271.

Ernst, E. (1998). Harmless herbs? A review of the recent literature. The American Journal of Medicine, 104, 170-178.

Farnsworth, N. R., Akerele, O., Bingel, A. S., Soejarta, D. D., & Eno, Z. (1985). Medicinal plants in therapy. Bulletin of World Health Organization, 63, 965-981.

Fillenbaum, G. G., Hanlon, J. T., Corder, E. H., Ziquba-Page, T., Wall, W. E., & Brock, D. (1993). Prescription and nonprescription drug use among black and white community-residing elderly. American Journal of Public Health, 83, 1577-1582.

Fillenbaum, G. G., Horner, R. D., Hanlon, J. T., Landerman, L. R., Dawson, D. V., & Cohen, H. J. (1996). Factors predicting change in prescription and nonprescription drug use in a community-residing black and white elderly population. Journal of Clinical Epidemiology, 49, 587-593.

Frate, D. A., Croom, E. M., Frate, J. B., Juergens, J. P., & Meydrech, E. F. (1996). Use of plant-derived therapies in a rural biracial population in Mississippi. Journal of the Mississippi State Medical Association, 37, 427-429.

Gormley, E. A., Griffiths, D. J., McCracken, P. N., & Harrison, G. M. (1993). Polypharmacy and its effect on urinary incontinence in a geriatric population. British Journal of Urology, 71, 265-269.

Gray, M. A. (1996). Herbs: Multicultural folk medicines. Orthopaedic Nursing, 15(2), 49-56.

Greenblatt, R. M., Hollander, H., McMaster, J. R., & Henke, C. (1991). Polypharmacy among patients attending an AIDS clinic: Utilization of prescribed, unorthodox, and investigational treatments. Journal of Acquired Immune Deficiency Syndromes, 4, 136-143.

Grymonpre, R. E., Mitenko, P. A., Sitar, D. S., Aoki, F. Y., & Montgomery, P. R. (1988). Drug-associated hospital admissions in older medical patients. Journal American Geriatrics Society, 36, 1092-1098.

Healthy People 2000 (1990). National health promotion and disease prevention objective, p. 67. Washington DC: US Department of Health and Human Services.

Helling, D. K., Lemke, J. H., Semla, T. P., Wallace, R. B., Lipson, D. P., & Cornoni-Huntley, J. (1987). Medication use characteristics in the elderly: The Iowa 65+ Rural Health Study. Journal of American Geriatrics Society, 35, 4-12.

Huxtable, R. J. (1990). The harmful potential of herbal and other plant products. Drug Safety, 5 (Suppl. 1), 126-136.

Ives, T. J., Bentz, E. J., & Gwyther, R. E. (1987). Drug-related admissions to a family medicine inpatient service. Archives of Internal Medicine, 147, 1117-1120.

Jonas, W. B. (1993). Evaluating unconventional medical practices. Journal of NIH Research, 5, 64-67.

Kart, C. S. (1994). The realities of aging: An introduction to gerontology (4th ed.), Boston: Allyn and Bacon.

Kassler, W. J., Blanc, P., & Greenblatt, R. (1991). The use of medicinal herbs by Human Immunodeficiency Virus-infected patients. Archives of Internal Medicine, 151, 2281-2288.

Kelner, M., & Wellman, B. (1997). Health care and consumer choice: Medical and alternative therapies. Social Science & Medicine, 45, 203-212.

Kronenfeld, J. J., & Wasner, C. (1982). The use of unorthodox therapies and marginal practitioners. Social Science of Medicine, 16, 1119-1125.

Lamy, P. P. (1986). The elderly and drug interactions. Journal of American Geriatrics Society, 34, 586-592.

Lassila, H. C., Stoehr, G. P., Ganguli, M., Seaberg, E. C., Gilby, J. E., Belle, S. H., & Echement, D. A. (1996). Use of prescription medications in the elderly rural population: The MoVIES Project. The Annals of Pharmacotherapy, 30, 589-595.

Lerner, I. J., & Kennedy, B. J. (1992). The prevalence of questionable methods of cancer treatment in the United States. CA, 42, 181-191.

LeSage, J. (1990). Polypharmacy in geriatric patients. Nursing Clinics of North America, 26, 273-289.

Lindley, C. M., Tulley, M. P., Paramsothy, V., & Tallis, R. C. (1992). Inappropriate medication use is a major cause of adverse drug reactions in elderly patients. Age and Ageing, 21, 294-300.

MacLennan, A. H., Wilson, D. H., & Taylor, A. W. (1996). Prevalence and cost of alternative medicine in Australia. Lancet, 347, 569-573.

Marwick, C. (1995). Growing use of medicinal botanicals forces assessment by drug regulators. Journal of American Medical Association, 273, 607-609.

May, F. E., Stewart, R. B., Hale, W. E., & Marks R. G. (1982). Prescribed and non-prescribed drug use in an ambulatory elderly population. Southern Medical Journal, 75, 522-528.

McCaleb, R. S. (1993). Regulation of dietary supplement: Hearing before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives (series no. 103-57). Washington, DC: 103rd US Congress, House of Representatives.

McGregor, K. J., & Peay, E. R. (1996). The choice of alternative therapy for health care: Testing some propositions. Social Science of Medicine, 43, 1317-1327.

Michocki, R. J., Lamy, P. P., Hooper, F. J., & Richardson, J. P. (1993). Drug prescribing for the elderly. Archives of Family Medicine, 2, 441-444.

Montamat, S. C., & Cusack, B. (1992). Overcoming problems with polypharmacy and drug misuse in the elderly. Clinics in Geriatric Medicine, 8, 143-158.

Montamat, S. C., Cusack, B. J., & Vestal, R. E. (1989). Management of drug therapy in the elderly. The New England Journal of Medicine, 321, 303-309.

Murray, J., & Shepherd, S. (1993). Alternative or additional medicine? Social Science of Medicine, 37, 983-988.

Murray, M. T. (1994). Natural medicine: A rational alternative. In M. T. Murray (Ed.), Natural alternatives to over-the-counter and prescription drugs (p. 29). New York: William Morrow and Company, Inc.

Musil, C. M. (1998). Gender differences in health and health actions among community-dwelling elders. Journal of Gerontological Nursing, 24(2), 30-38.

Musil, C. M., Ahn, S., Haug, M., Warner, C., Morris, D., & Duffy, E. (1998). Health problems and health actions among community-dwelling older adults: Results of a health diary study. Applied Nursing Research, 11(3), 138-147.

Nolan, L., & O'Malley, K. (1988). Prescribing for the elderly: Part I. Sensitivity of the elderly to adverse drug reactions. Journal of American Geriatrics Society, 36, 142-149.

Noyes, M. A., Lucas, D. S., & Stratton, M. A. (1996). Principles of geriatric pharmacotherapy. Journal of Geriatric Drug Therapy, 10(3), 5-35.

Panel on Definition and Description, CAM Research Methodology Conference, April 1995 (1997). Defining and describing complementary and alternative medicine. Alternative Therapies, 3(2), 49-57.

Paramore, L. C. (1997). Use of alternative therapies: Estimates from the 1994 Robert Wood Johnson Foundation National Access to Care Survey. Journal of Pain and Symptom Management, 13, 83-89.

Penninx, B., Guralnik, J. M., Simonsick, E. M., Kasper, J. D., Ferrucci, L., & Fried, L. P. (1998). Emotional vitality among disabled older women: The women's health and aging study. Journal of American Geriatrics Society, 46, 807-815.

Pollow, R. L., Stoller, E. P., Forster, L. E., & Duniho, T. S. (1994). Drug combinations and potential for risk of adverse drug reaction among community-dwelling elderly. Nursing Research, 43, 44-49.

Ranelli, P. L., & Aversa, S. L. (1994). Medication-related stressors among family caregivers. American Journal of Hospital Pharmacy, 51, 75-79.

Shimp, L. A., Ascione, F. J., Glazer, H., M., & Atwood, B. F. (1985). Potential medication-related problems in non-institutionalized elderly. Drug Intelligence and Clinical Pharmacy, 19, 766-772.

Shimp, L. A., Wells, T. J., Brink, C. A., Diokno, A. C., & Gillis, G. L. (1988). Relationship between drug use and urinary incontinence in elderly women. Drug Intelligence and Clinical Pharmacy, 22, 786-787.

Sills, J. M., Tanner, L. A., & Milstien, J. B. (1986). Food and Drug Administration monitoring of adverse drug reactions. American Journal of Hospital Pharmacy, 43, 2764-2770.

Simons, L. A., Tett, S., Simons, J., Lauchlan, R., McCallum, J., Friedlander, Y., & Powell, I. (1992). Multiple medication use in the elderly: Use of prescription and non-prescription drugs in an Australian community setting. The Medical Journal of Australia, 157, 242-246.

Sloan, R. W. (1992). Principle of drug therapy in geriatric patients. American Family Physician, 45, 2709-2718.

Stalker, D. F. (1995). Evidence and alternative medicine. Mt. Sinai Journal of Medicine, 62, 132-143.

Stewart, R. B. (1995). Drug use in the elderly. In J. C. Delafuente & R. B. Stewart (Eds.), Therapeutics in the elderly (2nd ed., pp. 174-189). Cincinnati, OH: Harvey Whitney Books.

Stewart, R. B., & Caranasos, G. J. (1989). Medication compliance in the elderly. Medical Clinics of North America, 73, 1551-1563.

Stewart, R. B., & Cooper, J. W. (1994). Polypharmacy in the aged: Practical solutions. Drugs & Ageing, 4, 449-461.

Stewart, R. B., Moore, M. T., May, F. E., Marks, R. G., & Hale, W. E. (1991). Changing patterns of therapeutic agents in the elderly: A ten-year overview. Age and Ageing, 20, 182-188.

Sutherland, L. R., & Verhoef, M. J. (1994). Why do patients seek a second opinion or alternative medicine? Journal of Clinical Gastroenterology, 19(3), 194-197.

Swonger, A. K., & Burbank, P. M. (1995). An overview of drug use and misuse among the elderly. In A. K. Swonger & P. M. Burbank (Eds.), Drug therapy in the elderly (pp. 28-34). Boston: Jones and Bartlett.

Taylor, D. (1996). Herbal medicine at a cross roads. Environmental Health Perspectives, 104, 924-928.

U.S. Bureau of the Census (1990). General population statistics. Economics and Statistics Administration. Washington DC: U.S. Government Printing Office.

U.S. Bureau of the Census (1996). Current population reports, special studies, Sixty-five plus in the United States. Washington DC: U.S. Government Printing Office.

U.S. Department and Health and Human Services (1997). Vital and health statistics: Prevalence of selected chronic conditions: United States, 1990-1992, Series 10: Data from the National Health Survey, No. 194, US Department of Health and Human Service, Centers for Disease Control and Prevention, National Center for Health Statistics, DHHS Publication No. (PHS) 97-1522.

Vincent, C., & Furnham, A. (1996). Why do patients turn to complementary medicine? An empirical study. British Journal of Clinical Psychology, 35, 37-48.

Waltz, C. F., Strickland, O. L., & Lenz, E. R. (1991). Measurement in nursing research (2nd ed.). Philadelphia: F.A. Davis Company.

World Health Organization (1993). Research guidelines for evaluating the safety and efficacy of herbal medicines: World Health Organization Regional Office for the Western Pacific, Manila; World Health Organization.

Workshop on Alternative Medicine (Chantilly, VA) (1994). Alternative medicine: Expanding medical horizons. A report to the National Institute of Health on alternative medical systems and practices in the United States. Washington, DC: U.S. Government Printing Office, Superintendent of Documents 1994.

Youngkin, E. Q., & Israel, D. A. (1996). A review and critique of common herbal alternative therapies. Nurse Practitioner, 21(10), 39, 43-46, 49-52.

APPENDIX A
QUESTIONNAIRE

QUESTIONNAIRE

INVESTIGATOR: SAUN-JOO YOON
COLLEGE OF NURSING
UNIVERSITY OF FLORIDA

DATE _____

INITIAL _____

ID # _____

ID#

PART A
HEALTH INFORMATION

A1 How would you rate your overall health:

1 — 1 — 1 — 1 — 1
1 — 2 — 3 — 4 — 5
Poor ————— Excellent

A2 How would you rate your physical health:

1 — 1 — 1 — 1 — 1
1 — 2 — 3 — 4 — 5
Poor ————— Excellent

A3 How would you rate your emotional health:

1 — 1 — 1 — 1 — 1
1 — 2 — 3 — 4 — 5
Poor ————— Excellent

A4 Have you visited a medical doctor or other health care provider in the past 12 months:

0. No 1. Yes
(If yes, continue to A5, and if the answer is no, go to A6 on next page.)

A5 What is the specialty of your doctor or health care provider? (You may have more than one.)

1. Family Practitioner
2. Internal Medicine
3. Surgeon
4. Gynecologist
5. Nurse Practitioner
6. Osteopath doctor (D.O.)
7. Others:

Now, I am going to read a list of *health problems or illnesses*. Please tell me if you have experienced this health problem in the past 12 months (Questions A6 through A28).

Go back to identified problems to determine seriousness. If it has been a problem, I would like to know how much it has interfered with your normal activities (Questions A29 through A51).

Go back to seriousness to determine the use of medications. Have you taken any medicines including prescription and over-the-counter drugs? If yes, I would like to know what kinds of medicines you have been taking to solve this health problem (Questions A52 through A74).

Problems		Illnesses	Seriousness*	Use of medications		Name of medications
No	Yes			No	Yes	
A6.	0 1	Allergies	A29. 1 2 3 4 5	A52. 0 1		
A7.	0 1	Anxiety	A30. 1 2 3 4 5	A53. 0 1		
A8.	0 1	Arthritis	A31. 1 2 3 4 5	A54. 0 1		
A9.	0 1	Back Problems	A32. 1 2 3 4 5	A55. 0 1		
A10.	0 1	Blood and circulatory problems	A33. 1 2 3 4 5	A56. 0 1		
A11.	0 1	Cancer	A34. 1 2 3 4 5	A57. 0 1		
A12.	0 1	Chronic pain	A35. 1 2 3 4 5	A58. 0 1		
A13.	0 1	Cold and flu	A36. 1 2 3 4 5	A59. 0 1		
A14.	0 1	Depression	A37. 1 2 3 4 5	A60. 0 1		
A15.	0 1	Diabetes	A38. 1 2 3 4 5	A61. 0 1		
A16.	0 1	Digestive problems	A39. 1 2 3 4 5	A62. 0 1		
A17.	0 1	Dizziness	A40. 1 2 3 4 5	A63. 0 1		
A18.	0 1	Fatigue (low energy)	A41. 1 2 3 4 5	A64. 0 1		

Problem	Illnesses	Seriousness*	Use of Medications	Name of Medications
No Yes			No Yes	
A19. 0 1	Gynecologic- al problems	A42. 1 2 3 4 5	A65. 0 1	
A20. 0 1	Headache	A43. 1 2 3 4 5	A66. 0 1	
A21. 0 1	Heart problems	A44. 1 2 3 4 5	A67. 0 1	
A22. 0 1	High blood pressure	A45. 1 2 3 4 5	A68. 0 1	
A23. 0 1	Lung problems	A46. 1 2 3 4 5	A69. 0 1	
A24. 0 1	Memory problems	A47. 1 2 3 4 5	A70. 0 1	
A25. 0 1	Obesity	A48. 1 2 3 4 5	A71. 0 1	
A26. 0 1	Skin problems	A49. 1 2 3 4 5	A72. 0 1	
A27. 0 1	Urinary problems	A50. 1 2 3 4 5	A73. 0 1	
A28. 0 1	Others:	A51. 1 2 3 4 5	A74. 0 1	

- Seriousness:

$\frac{1}{1} \text{-----} \frac{1}{2} \text{-----} \frac{1}{3} \text{-----} \frac{1}{4} \text{-----} \frac{1}{5}$
 not at all extremely serious

A75. Are you taking any other over-the-counter medicines or non-prescribed medicines?

0. No 1. Yes
 (If yes, list the name of medicines. _____)

A76. Now, I would like to ask you about use of some other kinds of remedies to take care of your health, particularly herbs. Have you ever used any type of herbs or herbal products in the last 12 months?

0. No 1. Yes

*Please, skip Part B and go to Part C if the answer to A75 is no. Continue the questionnaire Part B, if the answer to A75 is **yes**.*

ID# _____

PART B
INFROMATION ABOUT HERBAL PRODUCTS AND HERBS

B1. Now, I would like to know what kinds of herbs or herbal remedies you have used in the last 12 months. Could you list those?

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

B2. For what reason have you taken herbs or herbal products in the last 12 months?

1. to treat illness
2. to maintain or prevent any possible health problems
3. both 1 and 2

Now, I would like to ask you about each herbal product you mentioned above.

(Please use the Part B-1 Questionnaire to document each herbal product information.)

ID#

Part B-1 (Continued from Part B)

Now, I would like to ask you about each herb you mentioned above.

Name of the herbal product / herb:

B3.1 How do you use it?

0. internally 1. externally

B4.1 Did you prepare it at home to use it or buy it?

0. self-prepared 1. purchased

B5.1 What is the reason to use this herbal product / herb
(choose from 6 to 29)?

- | | |
|------------------------------------|--|
| 6. Allergies | 18. Fatigue(low energy) |
| 7. Anxiety | 19. Gynecological problems |
| 8. Arthritis | 20. Headache |
| 9. Back problems | 21. Heart problems |
| 10. Blood and circulatory problems | 22. High blood pressure |
| 11. Cancer | 23. Lung problems |
| 12. Chronic pain | 24. Memory problems |
| 13. Colds and flu | 25.Obesity |
| 14. Depression | 26. Skin problems |
| 15. Diabetes | 27. Urinary problems |
| 16. Digestive problems | 28. Others |
| 17. Dizziness | 29. maintain or prevent the possible health problems |

B6.1 Do you use this herbal product / herb continuously or only when you have symptoms?

0. continuously: how long _____ month
1. when symptoms have occurred: how many times a year
times

B7.1 How much do you think it is effective for you?

1. not at all
2. somewhat effective
3. very effective
4. don't know

B8.1 Have you experienced any type of side effect by using this herbal product / herb?

0. no 1. yes (specify) _____

B9.1 Where did you get the information about this herbal product / herb (may circle more than one)?

- | | |
|-----------------------------------|--------------------------|
| 1. family members | 2. friends and neighbors |
| 3. books or magazines | 4. TV, radio, newspapers |
| 5. computer internet | 6. health food stores |
| 7. health care providers | _____ |
| 8. alternative care practitioners | _____ |
| 9. others | _____ |

B10.1 How do you pay for it?

1. Insurance 2. Self-pay 3. Others _____

B11.1 Have you ever talked to your doctors or other health care providers about the use of this herb/herbal product?

0. no 1. yes (Whom did you talk to: _____)

ID# _____

PART C
DEMOGRAPHIC INFORMATION

- C1 DOB: ____ / ____ / ____
- C2 Are you:
1. married
 2. widowed
 3. divorced / separated
 4. never married
- C3 Do you consider yourself as:
1. White
 2. Black
 3. Hispanic-nonwhite
 4. Other _____
- C4 What is the highest grade or formal schooling you completed:
1. < High school
 2. High school
 3. < College graduate
 4. College graduate
 5. >Graduate school
- C5 Is your annual income:
1. < \$20,000
 2. \$20,000 - 34,999
 3. \$35,000 - 49,999
 4. > \$50,000
- C6 What is your religious preference:
1. none
 2. Protestant
 3. Catholic
 4. Jewish
 5. Other _____
- C7 What type of insurance do you have?
1. none
 2. Medicare
 3. Medicaid
 4. Private insurance
 5. Other _____

This is the end of the questionnaire. Thank you very much for your participation.

APPENDIX B
CONSENT FORM

Informed Consent to Participate in Research

**The University of Florida
Health Science Center
Gainesville, Florida 32610**

You are being invited to participate in a research study. This form is designed to provide you with information about this study. The Principal Investigator or representative will describe this study to you and answer any of your questions. If you have any questions or complaints about the informed consent process or the research study, please contact the Institutional Review Board (IRB), the committee that protects human subjects, at (352) 846-1494.

- 1. Name of Subject**

- 2. Title of Research Study**
Use of Herbal Products, Prescribed Medicines and Non-Prescribed Medicines Among Community-Dwelling Older Women

- 3. a. Principal Investigator(s) and Telephone Number(s)**

Saun-Joo L. Yoon, BSN, MSN (352) 392-3754

b. Sponsor of the Study (if any)
N/A

- 4. The Purpose of the Research**
The purpose of this research is to identify the use of herbs and/or herbal products for medicinal use, to compare differences in demographic characteristics and health status between herbal product users and non-users, and to identify the possible interactions between herbals with prescribed and/or non-prescribed medicines among community-dwelling older women.

5. Procedures for This Research

Your name was randomly selected from a list of women 65 years of age and over who live in Alachua County. When you responded 'yes, I will participate in the study', you were called to schedule a time and place for a short interview. You will be asked to read and sign a consent form to participate in the study and will have the right to decline without penalty. After an informed consent is obtained, you will be asked to answer the questions related to your health status, the use of prescribed and non-prescribed medicines, the use of herbal products, and demographic information. The entire interview will require approximately 15-30 minutes. Your name will not be used or placed on the interview form. A code number will be used on the form and only the investigator will have access to your name. All information you give will be kept confidential. All information will be grouped together and no person will be identified.

6. Potential Health Risks or Discomforts

There are no potential health risks or discomforts associated with this particular research study. If you wish to discuss these or any other discomforts you may experience, you may call the Principal Investigator listed in #3 of this form.

7. Potential Health Benefits to You or to Others

There will be no direct benefit to the subjects for participating in this study. However, the information that will be learned from this research will be beneficial to health care providers for better understanding the patterns of use of herbal products, and for more sensitive care for older women. The information that will be learned from this study will be beneficial for society in general to realize that there are potential risks of reactions or interactions by using herbal products alone or in combination with prescribed and/or non-prescribed medicines.

8. Potential Financial Risks

There will be no financial risks associated with this research.

9. Potential Financial Benefits to You or to Others

There will be no financial benefits associated with participating in this research.

10. Compensation for Research Related Injury: N/A

In the unlikely event of you sustaining a physical or psychological injury which is proximately caused by this study:

_____ professional medical; or _____ professional dental; or _____ professional consultative

care received at the University of Florida Health Science Center will be provided without charge. However, hospital expenses will have to be paid by you or your insurance provider. You will not have to pay hospital expenses if you are being treated at the Veterans Administration Medical Center (VAMC) and sustain any physical injury during participation in VAMC-approved studies.

11. Conflict of Interest

There is no conflict of interest involved with this study beyond the professional benefit from academic publication or presentation of the methods, results and conclusions of the study.

12. Alternatives to Participating in this Research Study

You are free not to participate in this study. If you choose to participate, you are free to withdraw your consent and discontinue participation in this research study at any time without this decision affecting your medical care. If you have any question regarding your rights as a subject, you may phone the Institutional Review Board (IRB) office at (352) 846-1494.

13. Withdrawal From this Research Study

If you wish to stop your participation in this research study for any reason, you should contact Saun-Joo L. Yoon at (352) 392-3754. You may also contact the Institutional Review Board (IRB) Office at (352) 846-1494.

14. Confidentiality

The University of Florida and the Veterans Administration Medical Center will protect the confidentiality of your records to the extent provided by Law. The Study Sponsor, Food and Drug Administration and the Institutional Review Board have the legal right to review your records.

15. Assent Procedure (if applicable): [Assent is the procedure used to obtain agreement to participate in the research from a subject, such as a child, who cannot give legal consent]

16. Signatures

Subject's Name

The Principal or Co-Principal Investigator or representative has explained the nature and purpose of the above-described procedure and the benefits and risks that are involved in this research protocol.

Signature of Principal or Co-Principal
Investigator or representative obtaining consent

Date

You have been informed of the above-described procedure with its possible benefits and risks and you have received a copy of this description. You have given permission for your participation in this study.

Signature of Subject or Representative

Date

If you are not the subject, please print your name _____
_____ and indicate one of the following:

- _____ The subject's parent
- _____ The subject's guardian
- _____ A surrogate
- _____ A durable power of attorney
- _____ A proxy
- _____ Other, please explain:

Signature of Witness

Date

If a representative signs and if appropriate, the subject of this research should indicate assent by signing below.

Subject's signature

Date

APPENDIX C
THE 20 MOST POPULAR ASIAN PATENT MEDICINES
THAT CONTAIN TOXIC INGREDIENTS

The 20 Most Popular Asian Patent
Medicines That Contain Toxic Ingredients

1. Product Name: Ansenpunaw Tablets
Manufacturer: Chung Lien Drug Works, Hankow, China
Toxic Ingredients: cinnabar (mercury chloride)
2. Product Name: Bezoar Sedative Pills
Manufacturer: Lanzhou Fo Ci Pharmaceutical Factory,
Lanzhou, China
Toxic Ingredients: cinnabar 2% or 10%
3. Product Name: Compound Kangweiling
Manufacturer: Wo Zhou Pharmaceutical Factory,
Zhe Jiang, China
Toxic Ingredients: centipede (scolopendra) 10%
4. Product Name: Dahuo Luodan
Manufacturer: Beijing Tung Jen Tang, Beijing, China
Toxic Ingredients: centipede (scolopendra)
5. Product Name: Danshen Tabletco
Manufacturer: Shanghai Chinese Medicine Works,
Shanghai, China
Toxic Ingredients: baronial
6. Product Name: Fructus Persica Compound Pills
Manufacturer: Lanzhou Fo Ci Pharmaceutical Factory,
Lanzhou, China
Toxic Ingredients: cannabis indica seed ()
7. Product Name: Fuchingsung-N Cream
Manufacturer: Tianjin Pharmaceuticals Corp.,
Tianjin, China
Toxic Ingredients: fluocinolone astound ()
8. Product Name: Kwei Ling China
Manufacturer: Changchun Chinese Medicines & Drugs
Manufactory, Chang Chun, China
Toxic Ingredients: cinnabar

9. Product Name: Kyushin Heart Tonic
Manufacturer: Kyushin Seiyaku Co., Ltd.,
Tokyo, Japan
Toxic Ingredients: toad venom, baronial
10. Product Name: Laryngitis Pills
Manufacturer: China Dzechuan Provincial
Pharmaceutical Factory,
Chengtu Branch
Toxic Ingredients: borax 30%, toad-cake 10%
11. Product Name: Leung Pui Kee Pills
Manufacturer: Leung Pui Kee Medical Factory,
Hong Kong
Toxic Ingredients: dover's powder (opium powder) ()
12. Product Name: Lu-Shen-Wan
Manufacturer: Shanghai Chinese Medicine Works,
Shanghai, China
Toxic Ingredients: toad secretion
13. Product Name: Nasalin
Manufacturer: Kwangchow Pharmaceutical Industry
Co., Kwangchow, China
Toxic Ingredients: centipede 5%
14. Product Name: Nui Huang Chieh Tu Pien
Manufacturer: Tung Jen Tang, Beijing, China
Toxic Ingredients: borneo camphor
15. Product Name: Niu Huang Xiao Yan Wan, Bezoar
Antiphlogistic Pills
Manufacturer: Soochow Chinese Medicine Works,
Kiangsu, China
Toxic Ingredients: realgar 19.23%
16. Product Name: Pak Yuen Tong Hou Tsao Powder
Manufacturer: Kwan Tung Pak Yuen Tong Main Factory,
Hong Kong
Toxic Ingredients: scorpion 10%
17. Product Name: Po Ying Tan Baby Protector
Manufacturer: Po Che Tong Poon Mo Um, Hong Kong
Toxic Ingredients: camphor 20%
18. Product Name: Superior Tabellae Berberini HCl
Manufacturer: Min-Kang Drug Manufactory, I-Chang,
China
Toxic Ingredients: berberini HCl ()

19. Product Name: Watson's Flower Pagoda Cakes
Manufacturer: A.S. Watson & Co., Ltd., Hong Kong
Toxic Ingredients: piperazine phosphate ()
20. Product Name: Xiao Huo Luo Dan
Manufacturer: Lanzhou Fo Ci Pharmaceutical Factory,
Lanzhou, China
Toxic Ingredients: aconite 42%

Source: Oriental Herb Association, State of California
Department of Health Services. January 28, 1992.

_ : requires doctor's prescription

Adapted from Workshop on Alternative Medicine (1994)

BIOGRAPHICAL SKETCH

Saun-Joo Lee Yoon received a Bachelor of Science in Nursing degree from the Seoul National University, Seoul, Korea in 1980. She received a Master of Science in Nursing degree from the University of Florida, Gainesville, Florida in 1992. Her professional experience includes oncology, medical, and orthopedic nursing. She also has experience in oncology nursing as a Clinical Nurse Specialist. She is a currently a member of Sigma Theta Tau International Honor Society of Nursing, Southern Nursing Research Society, and the Oncology Nursing Society.

I certify that I have read this study and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Doctor of Philosophy.

Claydell Horne
Claydell Horne, Chair
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I certify that I have read this study and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Doctor of Philosophy.

Kathleen Anne Long
Kathleen Long
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